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PRINCIPAL INVESTIGATOR: Anthony M. Digioia, M.D.

CONTRACTING ORGANIZATION: Shadyside Medical Center
Pittsburgh, Pennsylvania 15232

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Digioia, Anthony M., M.D.

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Shadyside Medical Center
Pittsburgh, Pennsylvania 15232

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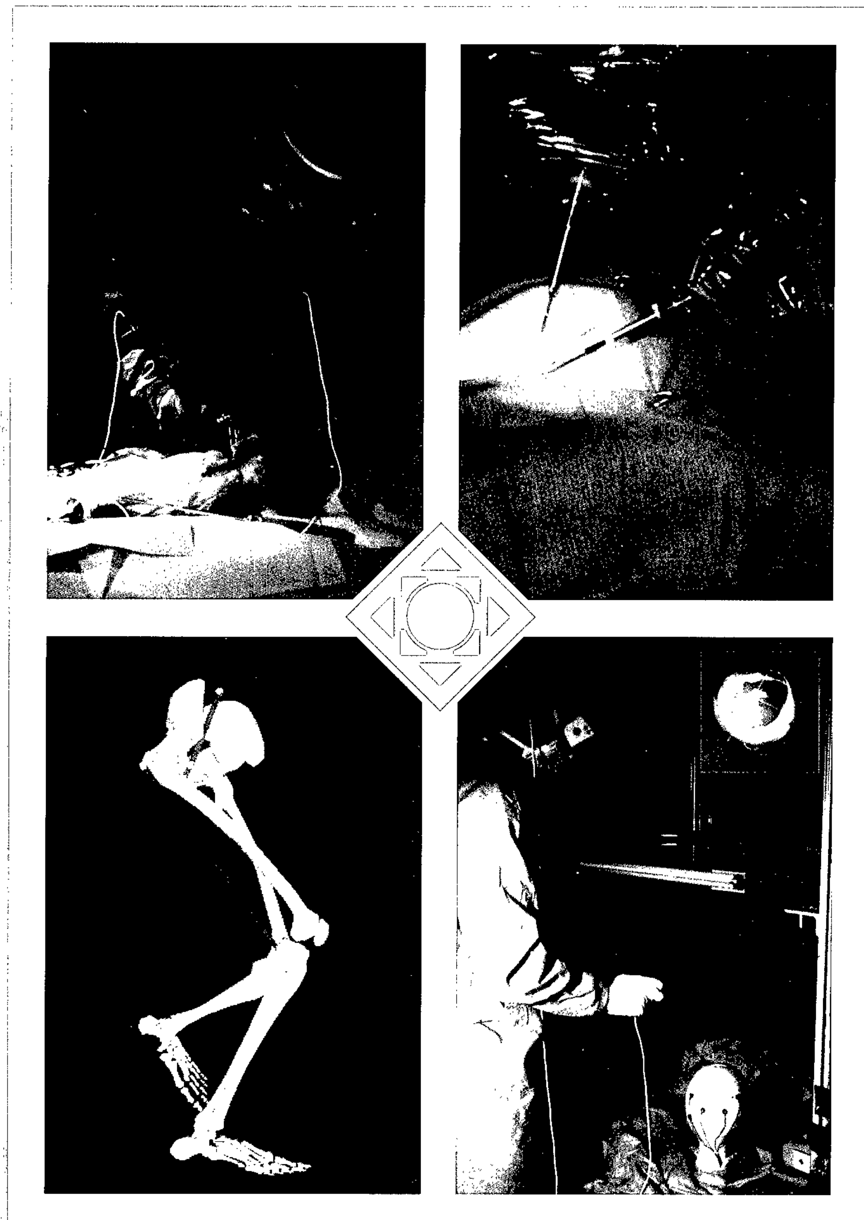
Second International Workshop on

Robotics and Computer Assisted Medical Interventions

Bristol, England
June 23-26, 1996



• Image Guided Therapy • Robotics •
• Surgical Simulators • Teleinterventions •

Final report for the Second International Workshop on:

Robotics and Computer Assisted Medical Interventions

RCAMI

• Image Guided Therapy • Robotics •
• Surgical Simulators • Teleinterventions •

June 23 - 26, 1996
Bristol, England

Workshop Organizers:

Anthony DiGioia, M.D.
Takeo Kanade, Ph.D.
Peter N.T. Wells, Ph.D., D.Sc.

Workshop Associates:

Frederick M. Morgan
David A. Simon

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Front cover:

Upper left: The HipNav system for image-guided orthopaedic surgery
(Carnegie Mellon University & Shadyside Hospital).

Upper right: Slave manipulator for the telepresense surgery system
(Stanford Research Institute).

Lower left: An anatomic / biomechanic lower body model with application to surgical simulation
(Scott Delp).

Lower right: Image overlay for augmented-reality display
(Carnegie Mellon University & Shadyside Hospital).

Workshop Contributors

United States:

National Science Foundation
Defense Advanced Research Projects Agency
U.S. Army Medical Research and Materiel Command
Mitsubishi Electric Research Laboratory
General Electric Company, Corporate Research and Development

United Kingdom:

Engineering and Physical Sciences Research Council
Medical Research Council
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Welsh Medical Technology Forum, Welsh Office
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Department of Trade and Industry

Other Contributors:

Philips Forschungslaboratorien, Hamburg
Siemens Erlangen, Germany
University of Bern, Switzerland
Computer Assisted Radiology (CAR)
DeeMed International, France

Foreword

Robotics and Computer Assisted Medical Interventions (RCAMI) has emerged as a rapidly evolving area of research and development with great potential for improving clinical outcomes while also reducing patient morbidity and the cost of health care. The first generation of computer-assisted systems are being utilized in operating rooms and hospitals throughout the world. Advancing RCAMI technology to the next levels of development and utilization requires collaboration among the disciplines of engineering, science and medicine. The RCAMI workshop brought together clinicians, engineers, scientists, and industrial representatives. Through intensive discussions, the participants defined current status and clinical applications of these technologies, and explored future directions and requirements.

The RCAMI Workshop was truly an international event that owes its success to the contributions of the participants, section leaders, and sponsors. We would like to thank those who participated in the workshop for their enthusiasm, dedication, hard work and their contributions toward the development of this report. We would also like to thank all of our sponsors, and especially the National Science Foundation and Gil Devey for providing the seed support and guidance in developing the concept for the workshop. Special thanks to our hosts in Bristol, England, the Special Trustees for the United Bristol Hospitals, for their graciousness and for helping us coordinate the workshop. We would especially like to recognize the effort and work performed by David Simon, Fritz Morgan, Joni Ropelewski and Jan Carne who were instrumental in putting together the pre-workshop and final reports, and coordinating the logistics of the workshop.

Eastwood Park provided the perfect venue for participants to get acquainted both professionally and personally. It was the spirit of the participants and the relationships that were developed during the workshop, that while difficult to capture in print, were among the most important elements of the workshop's success.

We are confident that the area of Robotics and Computer Assisted Medical Interventions will remain an exciting and expanding area with great potential to improve the clinical practice of medicine.

Thank you and we hope that you will enjoy reading the RCAMI report. We hope to see you in the United States for a followup workshop in 1998.

Anthony M. DiGioia, M.D.
Takeo Kanade, Ph.D.
Peter Wells, Ph.D., D.Sc.
Workshop Coordinators

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Section 1 - Executive Summary

The Second International Workshop on Robotics and Computer Assisted Medical Interventions (RCAMI) was held at Eastwood Park near Bristol, England, June 23-26, 1996.[1] The primary goal of the workshop was to bring physicians and researchers together to assess the current status, identify the future research needs and opportunities, and facilitate international collaboration and information exchange in the field of RCAMI. The workshop was organized by Anthony M. DiGioia III, Takeo Kanade, and Peter N.T. Wells, with assistance from Fritz Morgan and David Simon. Major support was provided by the National Science Foundation (NSF), the Defense Advanced Research Projects Agency (DARPA), U.S. Army Medical Research and Materiel Command, Engineering and Physical Science Research Council (UK), various commercial partners, and was hosted by the Special Trustees for the United Bristol Hospitals.

Participants were selected to provide equal representation from leading physicians and researchers in the RCAMI field, as nominated by their peers. Representatives from government and industry were invited and encouraged to present their agencies' missions, and to contribute in all workshop discussions.

Unlike many other similar workshops, substantive work was put in prior to the workshop. In preparation, participants were asked to submit three to five exemplary papers within their field of research, and to complete a questionnaire. A preliminary report was written by the organizers from these responses to define a starting point for workshop discussions. The report outlined a suggested set of issues; however, the workshop agenda was flexible to permit identification and discussion of other relevant topics by the participants.

We have divided the RCAMI field into four sub-areas:

1. *Image Guided Therapy* - the use of images obtained either during or prior to treatment, coupled with the use of computers, sensors, graphics, or other technologies to assist or guide the administration of treatment. For the purpose of this workshop, this group did not consider active or semi-active robotic systems, although many robotic systems employ image guidance to administer treatment.
2. *Robotics* - the intra-operative use of active or semi-active robotic/manipulation systems to significantly enhance the ability of humans to perform interventional procedures.
3. *Surgical Simulators* - the use of medical imaging, computer graphics, biomechanical analysis, and virtual environments, to simulate surgery for medical education, scientific analysis and pre-treatment planning.
4. *Teleintervention* - the application of information-based technologies to deliver procedural health care through an electronic interface. Indirect patient contact is implicit; however, the distance separating patient and physician may be insignificant, or great.

Workshop participants were divided into four groups, each concentrating on a particular application area, with each group assigned a physician and researcher as leaders. Roughly 70% of the workshop was devoted to group discussion, and the remaining time was spent addressing

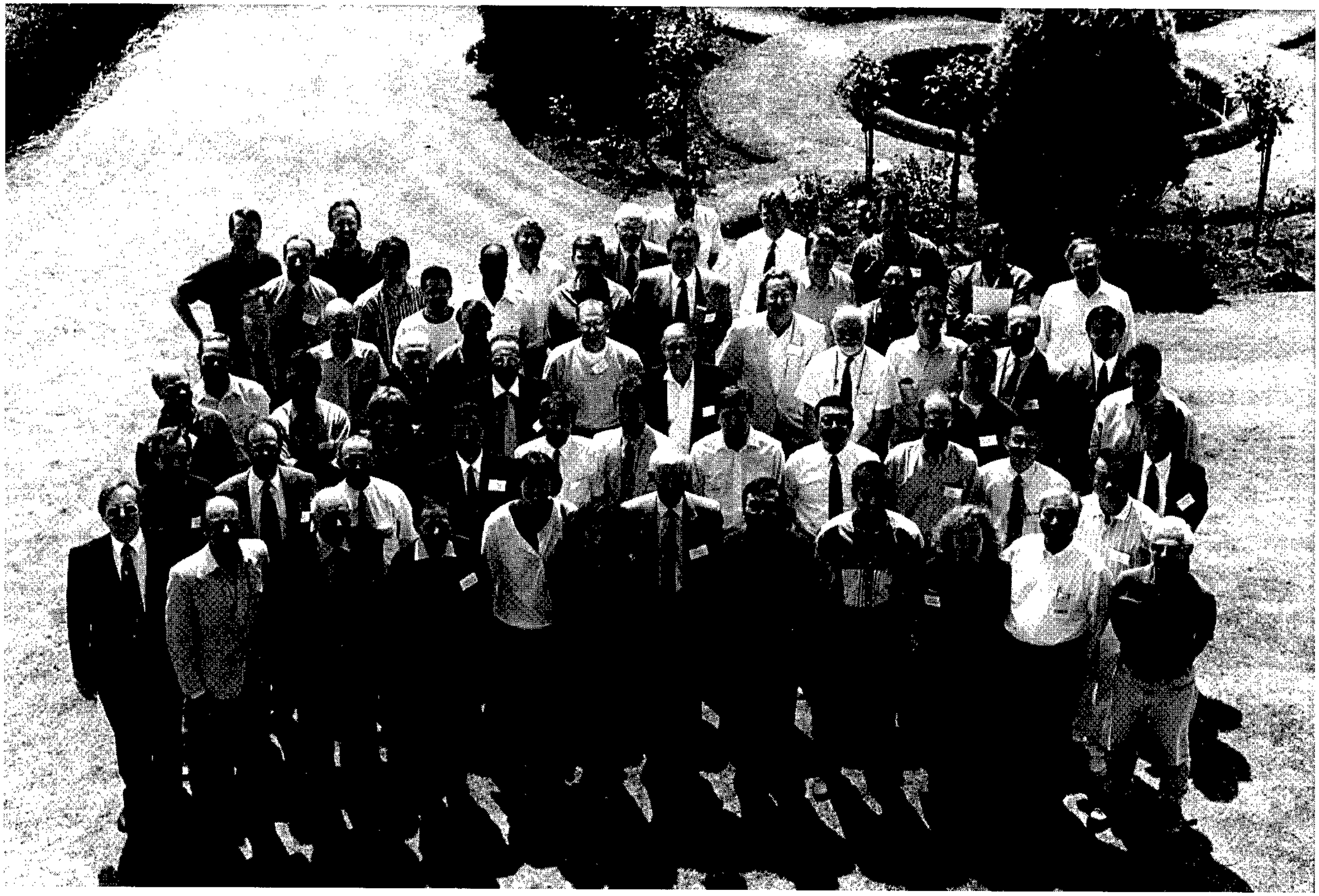
1. The first NSF Workshop on Computer-Assisted Surgery was held February 28 - March 2, 1993 in Washington, D.C., and was organized by Russell H. Taylor and George A. Bekey.

common issues. An important result of each working group was a list of technical and clinical challenges which must be met in order to advance the RCAMI field. Common themes identified from these lists include:

- *Soft tissue modeling* - the integration of models incorporating soft tissue characteristics into RCAMI systems. Technical challenges include: representation - defining the computational framework; segmentation - delineating soft tissue within 3-D medical images; generation - constructing the models; tracking - identifying soft-tissue movement in real-time during surgery; deformation - handling non-rigid structures; registration - establishing correspondence between two or more representations of a soft-tissue structure; and validation - ensuring model correctness.
- *Functional modeling* - the integration of physiologic and anatomic data into coherent models. This modeling enables exploration of functional consequences of a proposed intervention, examination of surgical options, optimization of techniques, and prediction of surgical outcomes.
- *Clinical validation* - demonstration of clinical benefit, cost reduction, and/or cost-effectiveness. Validation is critical for the development, justification, and clinical acceptance of RCAMI systems, yet no adequate measures of complex medical task performance have been developed.
- *Technical validation* - satisfaction of technical requirements. Key requirement areas include: accuracy of models, mechanisms, algorithms, imagers, sensors, and complete systems; usability of software and hardware interfaces and devices; safety to patients, users and developers; robustness of mechanisms, algorithms, and sensors. To minimize costs and avoid unnecessary complexity, task requirements must be carefully defined. New evaluation methods should be designed and applied to each new RCAMI system as it is developed.
- *Applied research* - fundamental RCAMI research problems should be studied in a manner which is closely coupled with the development and evaluation of clinical prototypes in key application areas. One area requiring significant work is the intelligent design of human-machine interfaces. For example, if a robotic system is to operate as a true "assistant" under a surgeon's supervision, it needs the ability to follow the surgical procedure as it progresses, to recognize organ systems, and to respond intelligently to the surgeon's high-level commands.

During the workshop, overviews of each application area were presented. There were also introductions to issues in safety, technology transfer, government regulations, and establishing common technical vocabulary. The application overviews provided a framework for inter-group understanding, while the common issue talks provided excellent structure for application-specific discussions within each group.

The workshop final report provides detailed information on workshop background, discussions, and recommendations, and should be read by any individual with an interest in the RCAMI area. In particular, researchers, physicians, members of funding agencies, policy makers, administrators, and industry representatives will find useful information in this document which will be published in several venues, including an electronic version on the World Wide Web (http://www.ri.cmu.edu/mrcas/rcami.html). It is recommended that a similar workshop be held in 2-3 years to re-evaluate the state of the RCAMI field.



The Participants of the Second International RCAMI Workshop at Eastwood Park near Bristol, England, June 26th, 1996

Section 2 - Report Overview

The RCAMI workshop report is organized as follows. Sections 3 - 6 contain the outcomes of individual working groups. Each section has a common structure:

- *Executive Summary* - A brief definition of the application area, followed by several key proposals for future research.
- *Definition* - An extended definition of the application area, possibly including background information.
- *Research Directions* - Outlines future research and clinical directions of this application area.
- *Review of Current Technology* - Summarizes the state-of-the-art in this application area.
- *Technical and Research Issues* - Describes the technical problems which must be solved for advancement of this application area.
- *Summary / Recommendations* - Working group conclusions and recommendations.

Small variations in the above structure may exist between working group reports, although each addresses all of the above issues.

The remainder of the report contains supplementary materials organized into several appendices. Appendix A contains a list of the workshop participants. Appendices B through E contain presentation materials from the keynote speeches in the four application areas. Appendices F through H contain materials from special presentations on safety, technology transfer and image-guided tumor diagnosis, respectively. Appendix I contains the working group framework provided to the participants in the pre-workshop report. Appendix J contains a summary of the questionnaire responses compiled for the pre-workshop report. Appendix K contains a checklist distributed to the participants to stimulate discussion. Appendix L contains a schedule of the workshop sessions. Finally, Appendix M contains a bibliography which was compiled from the list of "exemplary" papers submitted by each participant before the workshop.

Section 3 - Image-Guided Therapy

Chaired by: Richard D. Bucholz and Lutz P. Nolte

3.1 Executive Summary

Image-Guided Therapy - the use of images obtained either during or prior to treatment, coupled with the use of computers, sensors, graphics, or other technologies to assist or guide the administration of treatment. For the purpose of the workshop, this group did not consider active or semi-active robotic systems, although many robotic systems employ image guidance to administer treatment.

The following list represents the major proposed directions for future research initiatives in the area of Image-Guided Therapy:

- Development, validation and evaluation of clinical prototypes in key applications that merge enabling technologies. This would include development of modular components such as graphical user interfaces (GUIs), validation techniques, and user-machine interfaces to facilitate new image-guided therapy systems.
- Integration and characterization of soft tissue in image-guided therapy, including: segmentation, tracking, modeling, deformation, registration, and validation.

The image-guided therapy group consisted of four neurosurgeons, two radiologists, one cardiologist, one orthopaedist, one otorhinolaryngologist, two physicists, five engineers, three computer scientists, and four individuals representing either corporate or governmental entities. This combination is biased towards neurosurgeons and related disciplines, which influenced the nature of the discussions.

3.2 Definitions

This group's definition of image-guided therapy (IGT) includes three major components: a therapeutic object, a virtual object, and a navigational device (Figure 3-1). The therapeutic object consists of the patient (or parts of the patient) and an associated therapeutic modality. The virtual object is generated by means of modern imaging or signal sensing and processing. This includes diverse virtual objects such as endoscopic images. The navigational device enables precise therapy by utilizing the virtual object registered to the therapeutic object. Image guided therapy is based on an estimated transformation between the coordinate systems of the navigational device, and the therapeutic and virtual objects. Registration estimates this transformation. Calibration is typically required for the navigational device and the means of virtual object generation. This definition can be viewed as overly broad, but it must be non-specific to incorporate the full spectrum of imaging means now clinically available. This defi-

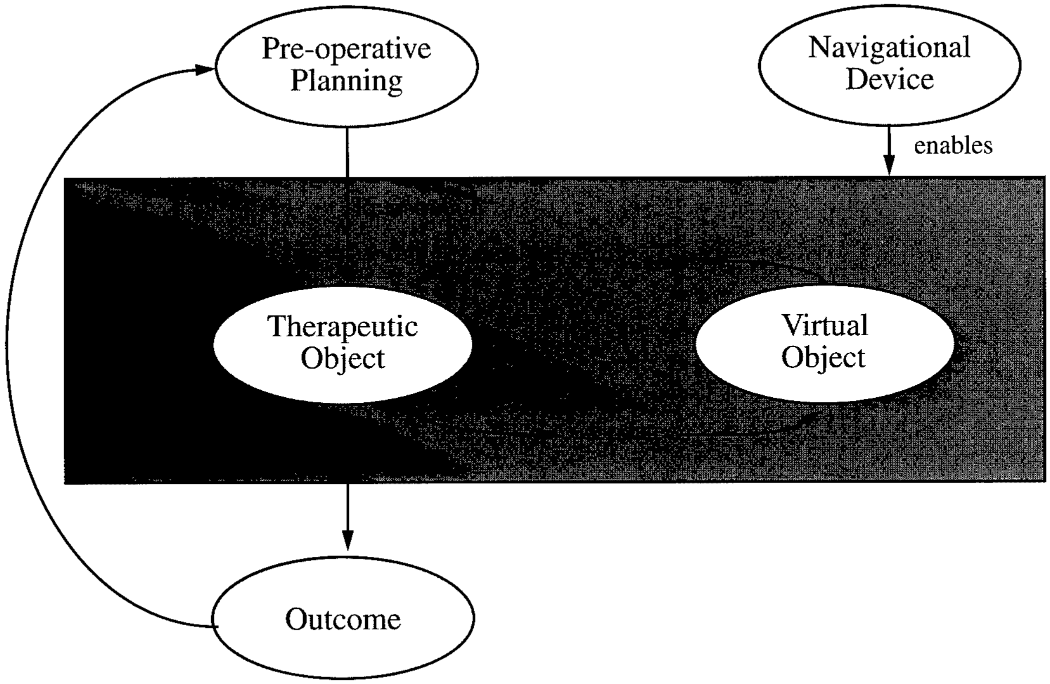


Figure 3-1: Schematic of Image-Guided Therapy

nition also includes the fabrication through lithography of objects which can be implanted within the patient to correct defects, such as the repair of skull defects using computer generated components. A particular image-guided therapy may employ multiple navigational devices, or multiple therapeutic and virtual objects.

Within an IGT system, registration can be performed using a variety of data types, as outlined in Figure 3-2. In particular, registration of the patient to pre-operative, intra-operative and post-operative data is possible. In order to perform an IGT, tools, effectors and/or therapeutic modalities must be registered to the patient as well.

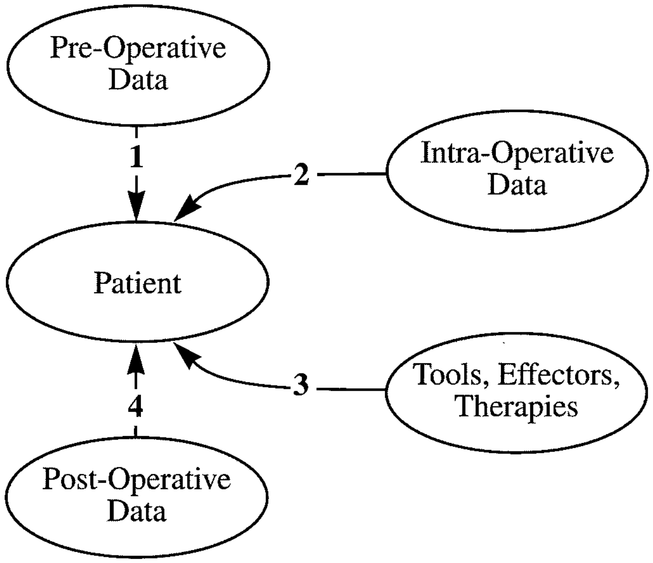


Figure 3-2: The registration process

Figure 3-3 shows a typical image-guided navigational system employing an optical digitizer (white horizontal bar at top of image) to track surgical instruments (in the surgeon's hand) modified by the addition of light emitting diodes (LEDs). In this application, a cranial procedure is being performed, and the head of the patient is tracked using a black arc equipped with LEDs attached to the patient's head (seen directly above surgeon's left hand). The position and orientation of the surgical instrument is displayed continuously on the large monitor on

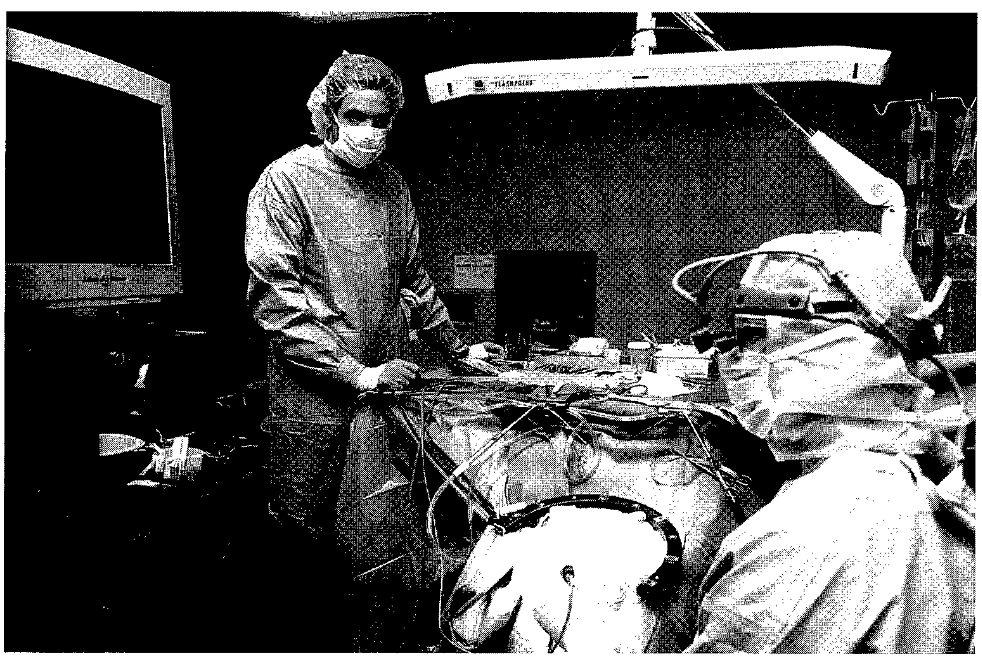


Figure 3-3: An image-guided navigational system (courtesy of Richard Bucholz).

the left. Such a system could be employed for other specialties simply by modifying the instruments and the device used to track the body part undergoing treatment. Figure 3-4 shows a second navigational system using similar components for accurately placing pedicle screws in spine surgery.

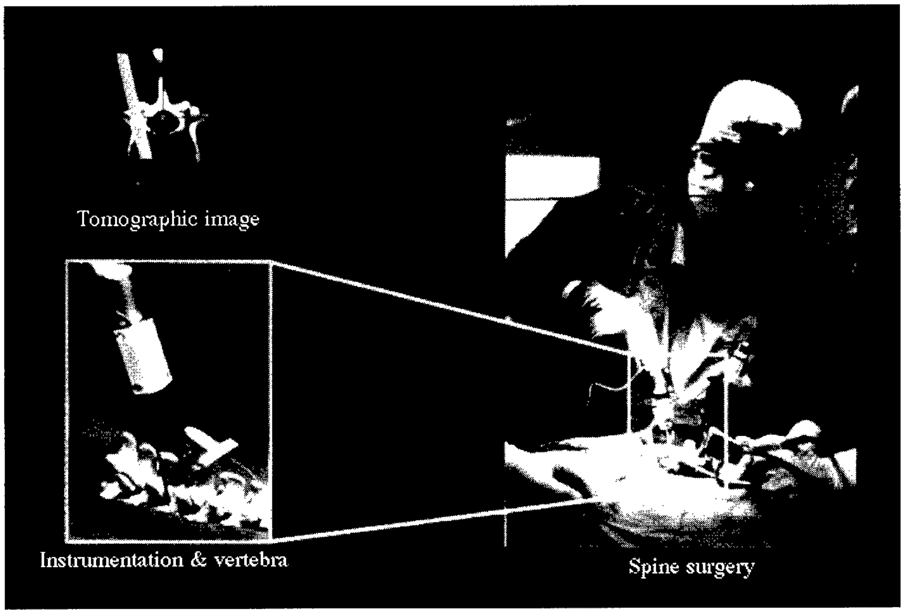


Figure 3-4: An image-guided navigational system for pedicle screw insertion (courtesy of Lutz Nolte).

3.3 Research Directions and Review of Current Technology

Applications in which IGT could be employed were extensively discussed. Applications can be classified by whether image guidance: 1) enables the procedure to occur or 2) allows the procedure to be performed either with greater safety, less invasiveness, improved efficiency, or lower cost. Examples of procedures which can only be performed by image guidance include functional neurosurgery, gene therapy, radiosurgery, and localized drug delivery. Examples of procedures which can benefit from image guidance include biopsy, tumor resection, ENT sinus procedures, joint reconstructions and replacements. Minimally invasive procedures often fall into the second category, as the application of image guidance permits reduced exposures and tissue dissection to accomplish the therapeutic goal. Procedures performed under real-time imaging, even those as simple as the use of fluoroscopy in orthopaedics, can be viewed as image-guided therapies. Key applications that are attractive in terms of incidence of disease in the population and desirability of image guidance were identified. They are grouped below by clinical application area.

It should be emphasized that there exists a tremendous discrepancy in the employment of image guidance across medical disciplines. In neurosurgery, image guidance is routinely

employed to permit functional interventions using framed stereotaxy, while other specialties have yet to develop initial applications. However, even in neurosurgery, a critical component of image guidance is the concept of interactivity, in which the surgeon interacts constantly with the virtual object and the navigational device during therapy. Fully interactive systems are just now being approved by government regulatory bodies and are becoming commonplace with neurosurgery.

3.3.1 General surgery

The application of IGT to general surgery is entirely dependent on registration and tracking of soft tissue, which is the target of most general surgical interventions. Therefore, the application to general surgery must await the development of techniques that can track soft tissue. Assuming that soft tissue can be handled, there are significant applications in procedures directed towards the liver, pancreas, kidneys, and pelvic structures. Of these applications a disease entity with a particularly high incidence involves obstruction of the biliary system. Cholecystectomy, which has already been improved by image guidance in the form of endoscopic intervention, could be further enhanced by tracking the soft tissues surrounding the gall bladder in real-time, increasing the safety and decreasing the amount of dissection needed for this common procedure. The staging of metastatic disease by image-guided minimally invasive techniques would reduce the suffering of patients with advanced cancer by reducing invasiveness.

Trauma to the abdomen and pelvis is rampant in the inner city population of the United States. Although CT scanning has advanced the management of abdominal trauma by detecting the presence of a perforation of a viscus, surgery for such an injury is carried out by traditional techniques in which the entire digestive system is exposed and manually inspected for tears. The development of imaging technologies which could reliably identify the location of a viscus tear, coupled to the surgical act through IGT, would have a tremendous impact on reduction of length of surgery (a critical concern in these medically unstable patients). IGT holds the promise of focusing treatment upon injured organs to repair the damage while sparing other organs from trauma caused by the surgical intervention.

Finally, breast cancer comprises one of the leading sources of early death in the female population. IGT has been applied to the breast with robotic biopsy devices. However, the advent of soft tissue tracking, registration, and modeling would enable fast, easy, and reliable breast biopsy with minimal discomfort to the patient, allowing for the rapid management of breast cancer.

3.3.2 Neurosurgery

Neurosurgery has a long list of procedures which are only possible using image guidance. Most of these procedures are grouped under the subspecialty created for this purpose, stereo-

tactic surgery. This field within neurosurgery has seen unparalleled growth fueled by tremendous advances in neurological imaging. Standard procedures within neurosurgery that rely on image guidance include: pallidotomy for Parkinson's Disease, biopsy of intracranial lesions, treatment of the same using focused irradiation (stereotactic radiosurgery), resection of intrinsic gliomas using frameless stereotaxis, and procedures upon the brainstem.

Image guidance has become so accepted within neurosurgery that most surgeons anticipate that all intracranial procedures will have some component of image guidance within the next five years. Key applications within neurosurgery will evolve around resections of lesions within eloquent cortex using real-time or pre-operative functional imaging to differentiate critical normal tissue from malignancies. Intractable epilepsy, with 50,000 new cases yearly within the United States, would become correctable by surgical resection if precise functional imaging is developed to detect abnormal tissue. Further, as new effectors are developed within neurosurgery, such as gene therapy for tumors, the delivery of these agents must be guided by high resolution, high definition images demonstrating the exact location of abnormal tissue.

Finally, image guidance will be applied to the spine, with emphasis on the proper positioning of spinal instrumentation (e.g., pedicle screws). Although image guidance is not enabling in this application, it can significantly reduce the complications of spinal instrumentation, which is increasingly employed to treat degenerative spine disease of our aging population.

3.3.3 Urology

Lesions of the prostate are an enormous clinical problem. It has been estimated that 1/3 of all men might benefit from a procedure on the prostate in their lifetime. Transurethral resection of the prostate (TURP), currently performed via an endoscope, has a significant failure rate of 1.5 to 1.8% yearly, requiring patients to undergo repeated operations. This failure rate is directly related to the amount of hypertrophied gland remaining; many studies have indicated that during a procedure only 38% of the gland on average is removed. More radical attempts to resect the prostate may result in perforation of the prostate capsule, which can lead to increased incidence of impotence postoperatively. The use of image guidance to track a resecting tool to ensure maximal resection of the prostate would have a dramatic impact on the failure and complication rate, and would be dependent on the development of soft tissue tracking and modeling methods.

Prostatic carcinoma is another urological condition resulting in tremendous disability and mortality. Many patients with tumor metastatic to the spine die paralyzed and incontinent, as these lesions tend to be resistant to palliative radiotherapy. The application of image guidance, so that radiation therapy could be focused upon the tumor and avoid the spinal cord, would relieve the suffering and deformity associated with this condition.

3.3.4 Cardiovascular Surgery

Coronary vascular disease is one of the major causes of death within our population. Three areas in which IGT could have an impact include: dilatation of the coronary arteries by intraluminal image-guided placement of vascular stents, resection of ventricular aneurysms guided by real-time imaging of the coronary wall to differentiate functional versus nonfunctional myocardium, and correction of cardiac arrhythmias by atrial interventions guided by intraprocedural sensing of abnormal cardiac conductivity. The effective treatment of these diseases using functional rather than purely image based data underscores the need to integrate all forms of data for IGT. The arrhythmia application relies upon the development of three dimensional models of cardiac transmission, and the development of miniaturized effectors which could block these pathways with high precision. Such applications could effectively treat atrial fibrillation, a common cardiac arrhythmia causing significant disability with the elderly.

3.3.5 Otorhinolaryngology

Sinus surgery is extremely common within our society, and in the majority of cases can be handled without image guidance (other than that provided by a nasal endoscope). However, there is an appreciable risk of inadvertent penetration of the cranial vault especially in cases in which the normal anatomy has been altered either through prior surgery or though disease progression. IGT could enhance the safety of such procedures by indicating the position of instruments within the nasal cavity and alerting the surgeon as the floor of the cranial vault is approached. A prime example of the fusion of robotic technology with IGT would be the attachment of a passive robot to surgical instruments allowing surgery only within the confines of nasal sinuses. Once the image-guided robot detected movement of an instrument outside of the sinus, it would become active, preventing further insertion of the instrument. This paradigm could be useful in other surgical procedures as well.

3.3.6 Orthopaedic Surgery

Orthopaedic surgery deals with degenerative, traumatic, and congenital disease of the locomotor apparatus. Therefore, the primary potential of IGT in this area focuses on therapeutic actions on bone rather than soft tissue. Example applications for which IGT augments existing capabilities are the insertion of pedicle screws or the functional placement of the acetabular cup in total hip replacement surgery. An example application in which IGT enables new procedures is surgical navigation combined with image fusion for spinal cage delivery. IGT in orthopaedics (as in other sub-specialties) is the key for combining advanced diagnosis, pre-operative planning, intra-operative tool actions, corrective procedures and postoperative evaluation. Examples are femoral or acetabular osteotomies. By incorporating biomechanical methods during pre-operative planning and intra-operative virtual object updating, significant improvements are possible via the optimization of biomechanical parameters.

Short term applications of IGT include the integration of IGT in conventional approaches for hip and knee replacement, and surgical interventions to cure low back pain, areas of overwhelming socio-economic importance. In the long term, IGT may have a significant impact on fracture fixation, if particularly fast, robust, and easy to handle systems become available. However, the dominant long term goal would be the development of minimally invasive techniques involving the delivery of novel implants and growth factor carriers.

3.4 Technical and Research Issues

3.4.1 Accuracy

Accuracy is perceived to be a major limiting factor to the broad application of image guidance. Accuracy in image guidance can be classified into three components: mechanical accuracy, application accuracy, and operational accuracy. Mechanical accuracy refers to the accuracy of the navigational devices; application accuracy refers to mechanical accuracy, the accuracy of the process by which the virtual object was obtained, and the accuracy of the registration process. Operational accuracy is application accuracy combined with errors introduced during the intervention. For example, tissue deformation during surgery markedly increases the inaccuracy of a procedure guided solely upon pre-operative imaging. For neurosurgical applications, the IGT working group concluded that mechanical and application accuracy of current systems are adequate for the majority of interventions, while operational accuracy is the key issue to be resolved. This conclusion is not necessarily applicable to other medical disciplines such as orthopaedics, for which existing registration techniques may not guarantee sufficient application accuracy. For all fields, increased accuracy is accompanied by increased cost and system complexity. Therefore, for any given application, the required accuracy should be carefully defined in order to minimize cost and avoid unnecessary complexity, while satisfying task requirements.

The consensus of the group is that operational accuracy in IGT requires improvement. Interactive real-time update of the virtual object during the procedure was identified as a key method for reducing operational errors. Conceptually, there are two ways to update the virtual object: repeated intra-operative imaging, and modeling of tissue behavior when subjected to therapy. Physical modeling may require tactile sensory feedback for predicting deformations. Intra-operative imaging can be performed using modalities such as MRI, CT, ultrasound, or fluoroscopy. For virtual object updating, the resolution of intra-operative imaging does not have to match that of the pre-operative imaging. Intra-operative ultrasound was mentioned as a technology which has desirable cost, availability, and accuracy characteristics. Neither method of virtual object updating has been sufficiently developed to allow for routine clinical use. The problem of modeling non-rigid therapeutic objects and the associated response to therapy is present throughout many medical disciplines, and is a key area for future research.

3.4.2 Other Issues

Several problems must be solved before widespread adoption of IGT is possible. Two of the most important are the level of human interaction required, and the ease with which IGT can be seamlessly integrated into the clinical environment. For IGT to be practical, medical images must be obtained quickly, and transmitted easily to the site of the intervention. Image data manipulation such as segmentation or multimodality fusion should be a standard function, and should be automated whenever possible. User interfaces for navigational devices, registration, and pre-operative planners should be simplified and standardized over diverse applications. In particular, user interaction during the registration process is a potentially troublesome area. Preferably, registration and associated data acquisition should be automated, such as in spinal registration using intra-operative planar ultrasonic or fluoroscopic images. However, in every case, the registration result should be verified by the surgeon. This may be technically difficult in closed (i.e., minimally invasive) procedures, and is an area for future research.

One concept discussed by the group was the development of robust middleware (i.e., standard IGT interfaces and components on which surgeons can be trained and use for a variety of procedures). Middleware would allow for plug-in modules to incorporate a variety of different functionalities (e.g., ability to interchange imaging modalities, input devices, algorithmic components, navigational devices, etc.).

Above all, widespread acceptance of IGT requires the demonstration of medical benefit, reduced cost, or both. The IGT group perceived that such a demonstration will be difficult to perform, and will be subject to controversy over the analysis used. Nevertheless, significant funding should be allocated to this important endeavor.

3.4.3 Enumeration of Technical Challenges

Table 3-1 contains an overview of the technical issues and challenges which must be solved before widespread adoption of IGT is possible. Each cell in the table represents issues related to a particular IGT functionality. Superscripts attached to particular issues indicate the timeframe during which it is expected that significant research will address the issue.

3.5 Summary / Recommendations

In conclusion, the group identified two key areas towards which research effort and funding should be focused. By focusing on these concepts, the effectiveness of limited research dollars could be greatly enhanced.

The first area is the development, validation, and evaluation of clinical prototypes in key applications that merge enabling technologies. This would include development of modular

Table 3-1: Technical Issues and Challenges in IGT Categorized by Functionality and Timeframe

<u>Pre-Operative Planning</u>
• Fully automatic, fast segmentation[2]
• Data fusion / integration of multiple data sets:[2]
  * Anatomic
  * Physiologic
  * Functional
• Dynamic soft-tissue modeling[3]
• Deformable atlases of human anatomy[2]
• Simulation[1,2,3]
• Image transfer optimization[2]
	<u>Action on Therapeutic Object</u>
	• Navigational devices and sensors[1,2,3]
	• End effector development
	  * Mini / micro[2,3]
	  * Conventional[1,2]
	• Minimally-invasive techniques[1,2,3]
	• Human computer interfaces[1,2,3]
	  * Display optimization
	  * Control devices
	• Real-time update[2,3]
	• Monitoring therapeutic delivery[1,2]
	• Linkage to robotics[3]
	• Linkage to teleinterventions[3]
		<u>Update of Virtual Object (2D & 3D)</u>
		• Advances in medical imaging[1,2,3]
		  * X-ray / fluoroscopic
		  * Ultrasonic
		  * CT
		  * MRI - static / real-time
		  * Micro-cellular imaging
		• Other techniques[1,2,3]
		  * 3D digitizer
		  * Video
		  * Range finders
		  * Active focused imaging
		  * Real-time 3D imaging

<u>Registration</u>[1,2,3]
• Speed
• Accuracy
• Patient motion
• Soft tissue deformation
• Percutaneous data collection
• Robustness
• Verification
• Types of registration:
  * 3D/3D vs. 2D/3D
  * Rigid vs. Non-rigid vs. Articulating
  * Geometry vs. Intensity
  * Fiducial vs. Non-fiducial
  * Artificial vs. Anatomic
  * Template-based
	<u>Outcomes</u>[1,2,3]
	• Clinical outcomes
	  * Long vs. short term
	  * Cost vs. benefit
	  * Outcome parameters
	    - primary: e.g. deg. of resection
	    - secondary: e.g. pain, life expectancy
	    - complication rates
	  * Serial imaging
	    - Intra-operative
	    - Post-operative
	    - Long-term re-evaluation
	  * Clinical trial models
	• Technical validation
	  * Common protocols
	  * System log of therapy
		<u>Common Issues</u>[1,2,3]
		• Human computer interfaces / Ergonomics
		• Standardization
		• Accuracy validation
		  * Clinical
		  * Technical
		• Applied prototype development
		• Inter-group collaborations
		• Training

Timeframe Key:
1 = Current work
2 = Near term (2-3 years)
3 = Long term (>5 years)

components, such as graphical user interfaces, system and component validation, and human-machine interfaces to facilitate new image-guided therapies. For example, with modular components, a system developed for cranial applications could be modified to track vertebral bodies during spinal fusion. This modification would require development of instrumentation appropriate for the spine, and a method to track the vertebral body. Minor modifications to the user interface would allow tracking of pedicle screws as they were inserted into the spine. With modular components, clinical feedback from one application can be used in other areas. In this way, new systems do not have to be developed from the ground up, and as new devices are developed (e.g., digitizers, microscopes, endoscopes) all applications can benefit.

The second area of research focus is the integration and characterization of soft tissue during image-guided therapy. This would include segmentation, tracking, modeling, deformation, registration, and validation of models. Subspecialities dealing with rigid structures (e.g., neurosurgery and orthopaedics) benefit from the ease of modeling and interacting with these structures. The absence of image-guided therapies for soft tissue procedures (e.g., abdominal surgery) is a direct result of the deformability of the associated structures and the difficulty associated with tracking these structures in real-time. As the ability to model and track soft-tissue improves, new applications will be developed in these areas.

Section 4 - Robotics

Chaired by: Russell Taylor and David Stulberg

4.1 Executive Summary

Medical Robotics - the intra-operative use of active or semi-active robotic/manipulation systems to significantly enhance the ability of humans to perform interventional procedures.

The following list represents the major proposed directions for future research initiatives in the area of Robotics.

- Emphasize development and validation of prototype systems targeted at specific applications that require significant advances in underlying component technologies such as sensing, manipulation, human-machine interaction, safety, model registration, etc. Research programs should be structured to encourage *close and continuing* teamwork between clinical end users, engineering researchers, and health economists.
- Provide means to facilitate the bridge from initial feasibility prototypes to systems that can be used as effective research and evaluation platforms and to promote more effective sharing of systems and technology infrastructure between researchers.
- Better means for evaluating computer-assisted surgical techniques must be developed. Many current clinical outcome measurement tools are inappropriate for the accurate evaluation of the efficacy of computer-assisted surgical technology.

4.2 Definitions

This group focused on computer-controlled manipulation devices and their application in surgery. There are two key roles for robotic systems in medicine:

- To optimize and extend the use of traditional human surgical skills in patient environments made accessible through the use of new technologies, such as endoscopic cameras. In addition, robotic technology is itself crucial in extending the applicability of minimally invasive and micro surgical techniques.
- To provide functional abilities that human surgeons lack. In particular, robotic systems can provide a crucial link between computer-based pre-operative planning and effective delivery of the planned therapy.

Humans and machines have complementary strengths and limitations, and the overall goal is to find ways to use them *together* to provide better and more cost-effective care than can be provided by either alone. Recognized advantages of robotic systems include:

- The ability to accurately position and reposition surgical tools.

- The ability to apply precisely calibrated forces.
- The potential for reduction in tremor as compared to human hands.
- The ability to scale the magnitudes of forces and motions to be either larger or smaller than are possible by humans.
- The ability to provide a stable platform for supporting and positioning surgical sensors, cameras, or instruments in a tireless manner.

Table 4-1: Complementary Capabilities

	Strengths	Limitations
Humans	• Good judgment • Strong hand-eye coordination • Integrate extensive & diverse information • Very flexible and adaptable • Very dexterous at "human" scale • Able to use qualitative information • Superb hand-eye coordination • Highly evolved • Easy to instruct (except teen-agers) • Explain themselves (ditto)	• Tremor • Fatigue • Limited manipulation ability & dexterity outside natural scale • Bulky • Geometric accuracy limited • Do not use quantitative information naturally • Hard to keep sterile • Susceptible to radiation, infection
Robots	• Good geometric accuracy • Untiring & stable • Potentially constructed in many sizes & immune to infection • Potentially not affected by radiation • Able to incorporate many sensors (chemical, force, acoustic, etc.) into control laws	• Poor judgment • Expensive • Technology is evolving • Difficult to instruct • Inscrutable • Limited ability to do complex control & hand-eye tasks

4.3 Review of Current Technology: Existing and Emerging Applications

A number of robotic devices have been developed for surgical use: assistive devices, navigational aids, positioning aids, and path following robots.

Robotic assistive devices have been developed. These devices aim to provide cost-efficient, stable control of surgical tools for tasks traditionally performed by surgical interns or other operating room personnel whose main job is to help the surgeon. The primary justifications for such systems include (a) cost savings by reducing the number of people in the operating room, (b) improved access to the patient, and (c) reduction in problems associated with human fatigue and inattention. Typical examples include:

- retractors
- endoscopic camera holders
- body part positioners

- needle holders
- etc.

The primary limitations of currently available devices are: 1) inability to respond in a user friendly, efficient manner to surgeons' current and anticipated needs; 2) size; and 3) lack of versatility. These systems are often cheaper and sometimes better at particular tasks than their human counterparts, but they are by no means as user friendly or flexible in what they can do.

A somewhat related class of emerging systems are those that *extend* a surgeon's manipulation capabilities, typically by permitting very accurately controlled small motions (e.g., for microsurgery) or by providing high degrees of dexterity within a confined space (e.g., for laparoscopic surgery). Such systems are typically teleoperated, although other control modes are possible, and are also discussed to some extent in the Teleinterventions section of this report (see Section Section 6 -). These systems have many uses even when the surgeon and robot are both within the same OR. They may also be used in "shared autonomy" modes to perform precise positioning and path control functions such as those below. Both the basic functional technology (sensing, actuation, control) and human-machine interfaces for these systems represent important research challenges. At one level, surgeons would really like the "nostalgic" feel of traditional open surgery while performing tasks requiring super-human precision, steadiness, or access to the patient's anatomy. At another level, there is a great opportunity to supplement such capabilities with additional unique functions based on pre-operative images or intra-operative sensing.

Robotic devices to aid <u>navigation</u> have been and are being developed. Generally, the primary advantage provided by such systems (often, rather over-broadly referred to as "computer-assisted surgery" systems) is accurate information of the position of surgical instruments relative to a patient's anatomy, as reflected in medical images. Although many of the issues associated with such systems are covered in the Image-Guided Therapy section of this report (see Section Section 3 -), there is strong synergy with "robotics". First, many of the key technologies (e.g., sensing, image-to-reality registration) associated with navigation are also crucial to more active robotic applications, and navigational systems are often used in conjunction with such systems. Second, active robotic devices can be used fruitfully as components in systems whose main function is navigation or information assistance (e.g., positioning of imaging devices or surgical microscopes). One of the main challenges for such systems is better integration with other operating room equipment and with pre-surgical planning.

A variety of systems have been and are being developed to <u>position</u> a surgical tool accurately and safely relative to the patient's anatomy. Examples include:

- inserting a needle into a calyx of the kidney
- stereotactic biopsy (brain, breast, etc.)
- percutaneous pattern therapy (brain, prostate, liver)

- drill guides (spine, skull, hip)
- total knee replacement guidance systems
- craniofacial surgery augmentation systems

Generally, the target position is determined from pre-operative 3D images (CT, MRI, etc.) or interactively from intra-operative 2D images (ultrasound, biplanar fluoroscopy). For cases in which pre-operative images are used, a number of techniques can be used to register the pre-operative data with intra-operative reality.

The main limitations with current positioning systems are: lack of sensitivity to soft tissues, inability to respond to changes in tissue character and motion; and limited ability to provide real-time intra-operative feedback to supervising clinical staff.

A number of systems have been created which generate a path through tissue. The advantage of these devices is the accuracy and reproducibility with which such paths can be made. Examples include:

- total hip replacement surgery.
- transurethral resection of the prostate.
- laser resection of brain tumors.
- high intensity focused ultrasound (HIFU) tissue ablation under real time MRI guidance.

Although there are exceptions, the main limitations of this group of robotic devices include: 1) cost; 2) size; 3) degree of integration of pre-operative and intra-operative planning; 4) registration methods; 5) lack of versatile end effectors; and 6) lack of versatility in general.

The next several pages contain images of several existing surgical robotic systems.

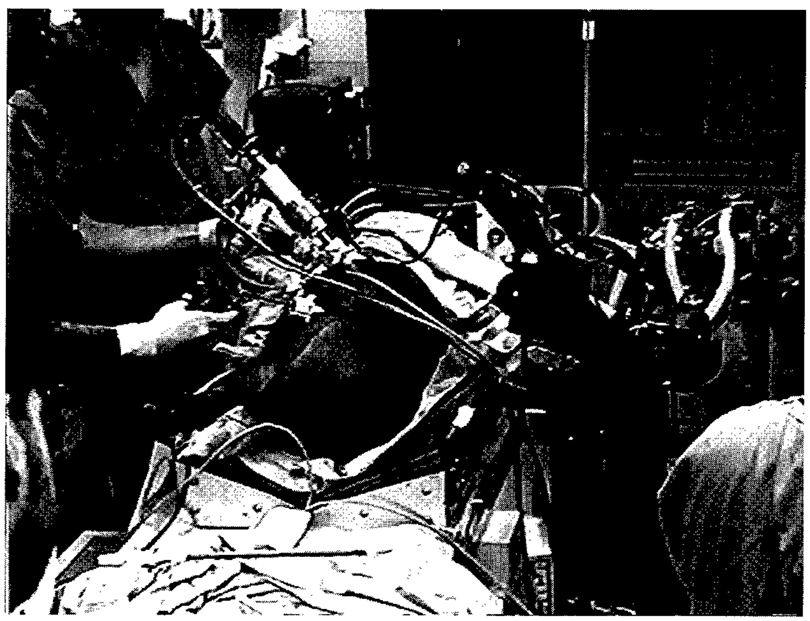
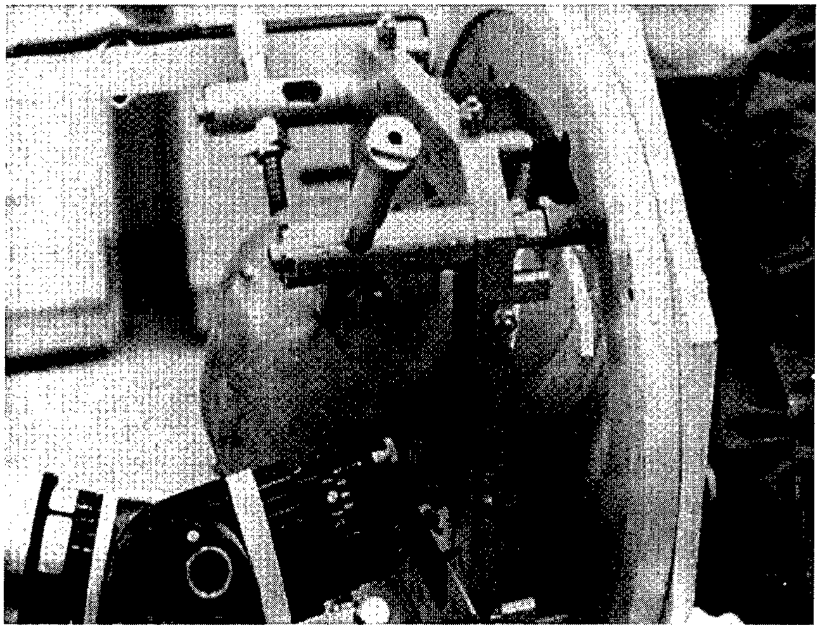


Figure 4-1: Robot systems for laparoscopic surgery. A number of assistive systems have been developed for laparoscopic surgery. The clinically deployed system on the top (AESOP, developed by Computer Motion, Inc.) positions a laparoscopic camera under surgeon joystick or foot pedal control. The experimental system on the bottom (developed by Prof. Taylor at Johns Hopkins University) performs similar functions using a joystick-like device clipped to the surgeon's instruments and also includes a number of autonomous positioning capabilities, such as the ability to position a surgical instrument on a target designated by the surgeon in video images.

Figure 4-2: Several groups are investigating the use of force compliant active robots in various shared autonomy modes to extend human manipulation capabilities. In the scene above, the surgeon is manipulating a neuroendoscope for evacuation of hematomas (developed at Johns Hopkins University).



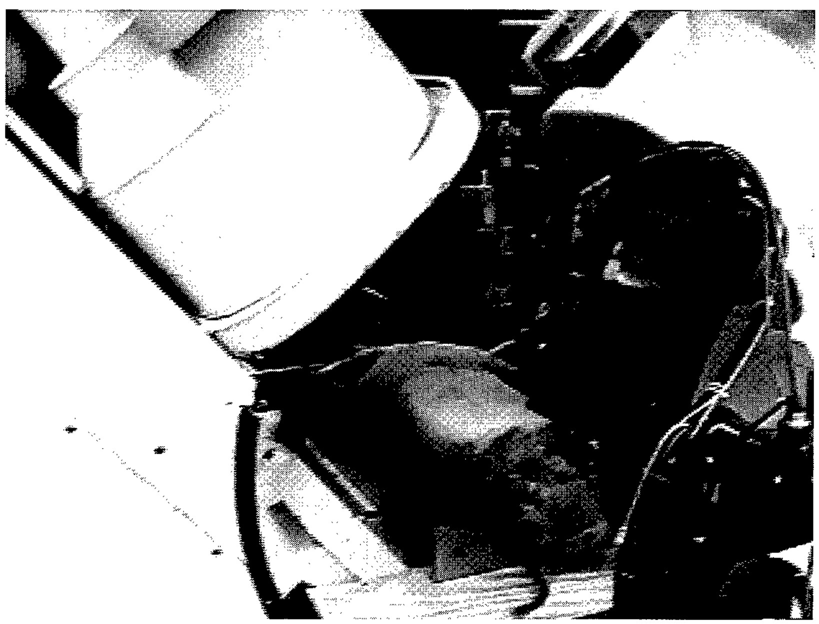


Figure 4-3: Typical robotic positioning applications. In the clinically applied system on the top (IGOR system developed by Stephane Lavallee), a robot is used to position a needle guide for stereotactic brain biopsies. Such applications rely crucially on the skull to provide a fixed frame of reference. In the experimental system on the bottom (developed by Profs. Anderson and Taylor at Johns Hopkins) the goal is to use the robot to place radiation pellets and other patterns of localized therapy under intraoperative biplanar fluoroscopic guidance into abdominal organs such as the liver and kidney. Significant advances in imaging, model registration, soft tissue modeling, and robotic systems will be needed to make such systems routinely usable. At the same time, robotic systems offer a potentially crucial advantage of being able to adapt quickly to achieve accurate placement in the presence of patient respiration and soft tissue deformation.

Figure 4-4: Path systems. In the picture on the top, a specialized robotic device is being used for transurethral prostate resection (developed by Prof. Davies et al., Imperial College and Guys Hospital, UK). The picture on the bottom shows a somewhat more versatile robot being used for cementless total hip replacement surgery (Robodoc developed by Integrated Surgical Systems).

4.4 Technical and Research Issues

4.4.1 Device Technology

Advances are needed in sensors, actuators, and mechanisms for tool positioning and tissue interaction. For minimally invasive surgery, it is necessary to develop systems that provide high degrees of dexterity in compact spaces ranging in size from 1-2 cm (intra-abdominal surgery) down to 1mm or less (e.g., for intravascular surgery) and for positioning them accurately both with "conventional" manipulators supporting instruments passed into the patient's body through small portals, and by means of devices that move through the patient's body (e.g., flexible endoscopes, catheters, semi-autonomous "crawlers"). Further advances are also needed for "conventional" microsurgical systems for such applications as eye surgery and microvascular surgery. There is also significant need to integrate a variety of sensors into surgical end-effectors and to integrate the information into the several levels of the system control hierarchy. One example of this would be integration of pressure sensors into tumor injection and biopsy devices. Another would be means to sense the hardness of bone in an orthopaedic bone machining application. This information would be used both to help control the tissue interaction process and as an input for updating registration of preoperative and intra-operative models.

4.4.2 Human-Machine Interaction

Better technology and methods are needed to support several forms of interaction between the human clinician and the computers controlling the robotic system. For *direct telesurgical control*, high bandwidth, high dexterity masters need to be developed that give the surgeon easy control of a variety of surgical devices and end-effectors and that provide suitable proprioceptive and haptic feedback (see Section 6.0 on Teleinterventions). For *supervisory control* of assistive and precise surgical devices, natural methods for communicating the surgeon's intentions without imposing an undue burden on the surgeon's attention must be developed. Communication with a robotic assistant should be no more difficult than communicating with a human assistant. Indeed, the robotic system should be able to "understand" and (in some cases) anticipate the surgeon's intentions, by relating commands to models of the patient anatomy and task plan. This capability will require both significant advances in the ability of systems to model and monitor surgical procedures (discussed below) and significant advances in ways to use such models in conjunction with a variety of novel and existing technologies for commanding and advising the systems.

It is similarly crucial that the robotic system be able to report its understanding of the current surgical situation in terms the surgeon is familiar with. One crucial challenge will be to find ways to communicate the *limitations* (e.g., in registration accuracy) of the system's model without confusing the surgeon to the extent that the information conveyed is useless. Existing

techniques (e.g., superimposed displays) need to be substantially improved and new methods, not yet thought of, may have to be invented.

In cases where the robot is used to *augment* the surgeon's manipulation capabilities, rather than simply provide assistive functions, significant advances in telemanipulation methodology may be required. Better means must also be developed for coupling human judgement with machine consistency and stability in precise surgical manipulation tasks. This will require the development of good methods for the human surgeon and control computer to *share* control of robotic devices and to "hand-off" control from one to another in a graceful manner.

4.4.3 Integration with information infrastructure

Improved methods for modeling patient anatomy and surgical state are crucial, including: methods for modeling deformable organs and structures based on pre-operative data; methods for updating these models based on real-time sensing; and methods for predicting how tissue will respond to manipulation forces.

A related crucial issue concerns accuracy. Accurate control of assistive manipulation tasks such as retraction or countertraction will be substantially improved by good dynamics models of the tissues being manipulated. Likewise, such tasks as accurate placement of needles into solid organs and tumors may require good means for modeling and adapting to tissue deformation during the treatment process. The system's internal model needs not only to represent its best current guess of the patient geometry, but also possible modeling errors. Application software needs to make use of this information both in planning and in assuring safe execution of planned tasks.

4.4.4 Safety

Safety is a crucial consideration in surgical applications. Development of appropriate guidelines for safety, and determination of which techniques are appropriate in particular situations remain open areas for future work. In addition, better methods for modeling intra-operative anatomy and its relationship to the robotic equipment should be developed for improving patient safety. For example, safety can be improved by identifying dangerous regions and requiring an explicit override from the surgeon before permitting a surgical cutter or instrument to enter them. Similarly, models of system registration error are crucial in planning and executing precise biopsies, tissue resections, and similar procedures.

4.4.5 Integration into the operating room environment

The successful introduction of robotic systems in the near future requires that the systems be compatible with current operating room environments. However, truly complex, interactive robotic systems will require significant reconfigurations of the current operating room concept. This reconfiguration is essential to the successful integration of planning, registration,

tooling and evaluation technologies. The sooner that computer-assisted surgery compatible operating room (CASCOR) concepts are conceived and developed, the sooner medically specific robotic technologies can be introduced into the operating room.

In addition to providing a user friendly environment for robotic devices, CASCORs will have to address such issues as sterilization of microsensors and other robotic devices, the potentially unique electrical requirements of complex computer technology, and the ability to transition an operating room between computer-assisted and conventional surgical procedures.

4.4.6 Evaluation and Assessment

Robotic technologies will and should be critically evaluated in terms of cost-effectiveness. Many current clinical outcome measurement tools are inappropriate for the accurate evaluation of the efficacy of computer-assisted surgical technology. There is the potential to create methods for evaluating the efficacy of computer-assisted surgical techniques (e.g., finite element modeling, microvascular flow rates, implant positions). New and appropriate evaluation methods should be designed and applied to each new computer-assisted surgical application as it is conceived and developed.

4.5 Summary / Recommendations

1. ***Research model*** - Emphasize development and validation of prototype systems targeted at specific applications that require significant advances in underlying component technologies such as sensing, manipulation, human-machine interaction, safety, model registration, etc. In developing such systems, active teamwork between clinicians and technologists is crucial at all stages to identify and evaluate key advantages from the application of robotic technology to the clinical problem being studied. Similarly, issues of cost-effectiveness and eventual deployment should be understood from an early stage, and early participation by industry should be encouraged. Great attention should be paid to early in-vivo and clinical validation of results, both to provide better understanding of actual needs and as a means of strengthening communication between members of the team.
2. ***Enabling technology research*** - Research to develop critical enabling technologies and techniques should be pursued aggressively. Although this research will most often be best pursued within the context of an integrated system targeted at a particular application, many topics have very broad applicability and more broadly focused research may sometimes be appropriate so long as the link to eventual application is clearly understood and proper validation of results is possible. A few specific goals of particular interest to our working group include:
   a) Significantly extend the ability of robots to perform surgical tasks such as retraction, dissection, or accurate placement of needles into deformable soft tissues or organs. This will require:

   i) Research to determine mechanical properties of various soft tissues and organ systems, in particular force-displacement-velocity relationships. In addition to being essential for modeling and sensing soft tissue deformations, this work may provide insight into new ways for interacting with such tissues.

   ii) Development of means to sense (as well as model) deformation of soft tissues during manipulation, particularly organs without clear visible surface landmarks (e.g., kidney, liver, lung). This will permit robots to autonomously manipulate tissue (dissection, puncture, etc.).

   iii) New methods for integrating models and sensory information to perform specific surgical tasks.

b) Develop new robotic manipulators for specific surgical tasks and contexts. For example:

   i) For minimally invasive surgery, develop systems that can provide full six-degree-of-freedom motion at the target tissue despite limited access through small incisions or through internal body pathways such as the GI tract, the bronchial tree, or the cardiovascular tree.

   ii) For microsurgery, provide high dexterity, precise, and delicate motion without requiring large end effectors or compromising safety or sterility.

   iii) For image-guided surgery, develop new manipulators that can work precisely but unobtrusively with a variety of imaging equipment such as fluoroscopic C-arms and biplanar devices, CT & MRI scanners, and 3D ultrasound.

   iv) Development of low-cost, compact systems for multiple applications that can work with very high reliability and that can be easily sterilized using commonly available means such as autoclaving.

c) Substantially enhance the "higher level" control available for robotic systems in the operating room, to enable them to function more as surgical assistants rather than only as teleoperated slaves. This will require:

   i) Development of means for characterizing common surgical tasks in terms of models of patient anatomy.

   ii) Development of means for updating these models from intra-operative information and for interpreting surgeon commands, based on the current surgical context.

   iii) Human-factors research to determine what surgeons actually do and feel when they perform various procedures. In addition to providing essential information for research on assistive systems, such information will be generally useful in establishing performance criteria for surgical robots. For example, the rapid growth of laparoscopic surgery reveals that force information and full six degree-of-freedom (DOF) mobility are not essen-

tial for some procedures. What additional procedures are possible if limited force information is available? With high-fidelity force feedback? With an additional DOF, or more than six DOF?

iv) Integration of this information into "higher level" controls extending traditional teleoperation into various forms of supervised autonomy. One particular challenge for such systems will be how to preserve safety and verification of surgeon intentions without becoming unduly burdensome on the surgeon.

3. ***Grand Challenges*** **-** The robotics task force spent only a limited amount of time discussing possible "grand challenge" applications that might be used to motivate some of the above research. These possibilities represent one natural evolution:

   a) "Robotic intern" - A system that can perform many of the same manipulation functions now performed by novice surgical personnel, such as scope pointing and retraction. Key characteristics and research challenges: natural interface (speech recognition, grab-and-move), low cost, small OR footprint.

   b) "Nostalgic telesurgery surgery" - A system for minimally invasive surgery that restores to the surgeon the full dexterity, mobility, and sensitivity enjoyed in open incision procedures. The system would work through small incisions or intraluminally, but the surgeon would not experience constraints of present endoscopic or catheter-based techniques. Key characteristics and research challenges include dexterous and compact manipulators (both master and slave); visual, force and distributed tactile feedback; natural user interface; and safety.

   c) "Robotic resident" - A system that can perform as well as a surgical resident in mid-training in performing specific tasks under the supervision of an experienced surgeon. This would require a semi-autonomous robot which incorporates extensive sensing and planning, can dissect tissue, suture, etc. Sensing and control issues are paramount for construction of such a system and include how to deal with soft tissue, sense state of procedure, re-plan in real time, interact with surgeon, safety, etc.

   d) "Super-delivery" - A versatile robotic system, integrated with a configurable variety of intra-operative and pre-operative imaging modalities, capable of navigating a minimal damage path, and accurately delivering a pattern of localized therapy into arbitrary soft tissue lesions.

4. ***Evaluation*** **-** Better means for evaluating computer-assisted surgical techniques must be developed. Many current clinical outcome measurement tools are inappropriate for the accurate evaluation of the efficacy of computer-assisted surgical technology. In developing appropriate measures, active participation by clinicians, technology researchers, and human-factors experts are all essential.
5. ***Infrastructure*** **-** Support development, replication, and sharing of common systems infrastructure and component subsystems to promote research, and to simplify eventual clinical qualification and deployment of the results of research.

a) As in many areas of research, medical robotics teams often must spend considerable effort building up the necessary infrastructure of proven components (robots, sensors, end-effectors, systems software, registration algorithms, etc.). Because of safety and other considerations, the delay and cost associated with this activity are even more pronounced than in other areas of robotics research and can be a definite impediment to entry into the field. Some specific steps that might be taken include creation of common interfaces and exchange standards, hardware and software engineering activity to facilitate sharing of components, and encouragement of "pooled" equipment acquisitions and shared software development to amortize costs and promote interchange of results and techniques.

b) Similarly, robotic devices have significant potential to *enable* development of novel therapeutic methods that can significantly improve both clinical outcomes and reduce costs. However, such synergistic research requires a more rigorous level of engineering than is commonly found in typical technology-oriented academic research, and it is crucial to provide a bridge between initial feasibility prototypes and systems that are effectively usable without constant attendance by their original implementors.

6. ***Safety*** **-** Appropriate safety architectures and procedures need to be implemented in any medical robotics or computer-assisted surgical system. In determining what is appropriate, it is important to consider the potential for harm, and the risks inherent in conventional manual procedures. Further, computer-controlled medical devices themselves raise a number of important research issues, as discussed in Section 4.4.4, that should be pursued within the context of specific applications and systems.

Section 5 - Surgical Simulation

Chaired by: Scott Delp and Ferenc Jolesz

5.1 Executive Summary

Surgical Simulation - the use of medical imaging, computer graphics, biomechanical analysis, and virtual environments to simulate surgery for medical education, scientific analysis and pre-treatment planning.

The following list represents the major proposed directions for future research initiatives in the area of Surgical Simulation:

- Incorporation of functional models into existing anatomical models. The development of physiologically-based models will allow us to create more realistic and useful surgical simulations in which the functional consequences of a proposed intervention can be predicted, surgical options can be explored, and results optimized. This new development will have widespread applications in medical education, scientific research, patient care, and many non-surgical applications.
- A "grand-challenge" for surgical simulation is to create a virtual human body that allows one to learn not only normal and abnormal anatomy and physiology, but also to dissect anatomical structures, simulate medical interventions, and predict outcomes for a wide variety of procedures and situations (e.g., automobile accident). The virtual human model would serve as a fantastic virtual laboratory for research and education, decreasing the need for animal and cadaver experiments in medical education and training.
- The development of new surgical simulators will be accelerated by capitalizing on advances in related fields, such as medical imaging, computational modeling, and virtual environments.

5.2 Definitions

We have defined surgical simulation in three broad areas as outlined in Figure 5-1. The first area, training systems, may be comprised of software-based simulations exclusively, or a combination of hardware and software elements. The second area comprises tools for scientific analysis. This includes tools to design procedures and implants, to predict outcomes, and to assess failure and success of an intervention. The third area is surgical pre-planning for the purpose of performing an actual procedure with the assistance of robots, trackers, jigs, endoscopes etc. Thus, surgical simulation is a first step in most image-guided and robot-assisted surgeries. The boundaries between these three areas are not distinct. For example, a well-tested training system may be used to plan a surgery by substituting actual patient data for an idealized computer model of the patient.

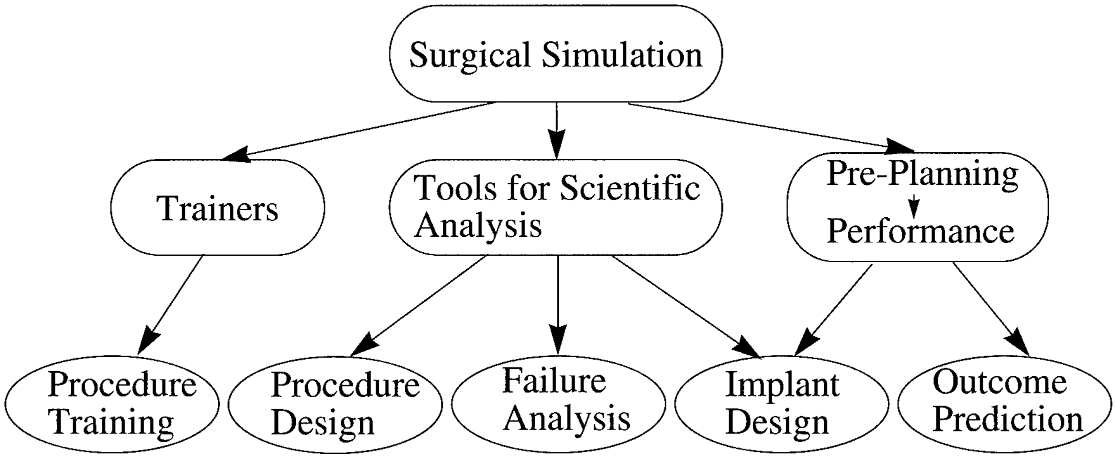


Figure 5-1: Taxonomy for surgical simulation

Figure 5-2 shows an anatomical and biomechanical model of a human lower body which can be used to help explain the causes of movement abnormalities and predict the functional consequences of surgical interventions. This type of functional simulation has significant potential for application in the area of surgical simulation.

5.3 Research Directions and Review of Current Technology

Surgical simulations have provided demonstrable benefits in several areas. For example, in craniofacial reconstruction, surgical pre-operative planning decreases operative times, predicts postoperative geometry and improves surgical outcomes. In neurosurgical applications, tumors can be accurately located and removed without damage to healthy tissue. However, current applications are limited to simple anatomical models. Creating a more comprehensive anatomical/physiological model would allow evaluation of the functional consequences of a proposed surgery, and serve as a test-bed for a wider variety of applications. For example, the post-operative capacity of an organ system could be estimated after tumor removal. Surgical simulators may also replace the trial-and-error process of training and accelerate the acquisition of experience by clinicians.

Figure 5-3 outlines four components of a surgical simulation model which we feel would be necessary to develop the full potential of this technology. These components include information about normal anatomy, physiology and pathology, biomechanics and biology.

Development of the technology necessary to construct the proposed "grand-challenge" virtual human model has several important benefits. Computer graphics models of the body provide an effective vehicle for communication with patients so that they can understand proposed

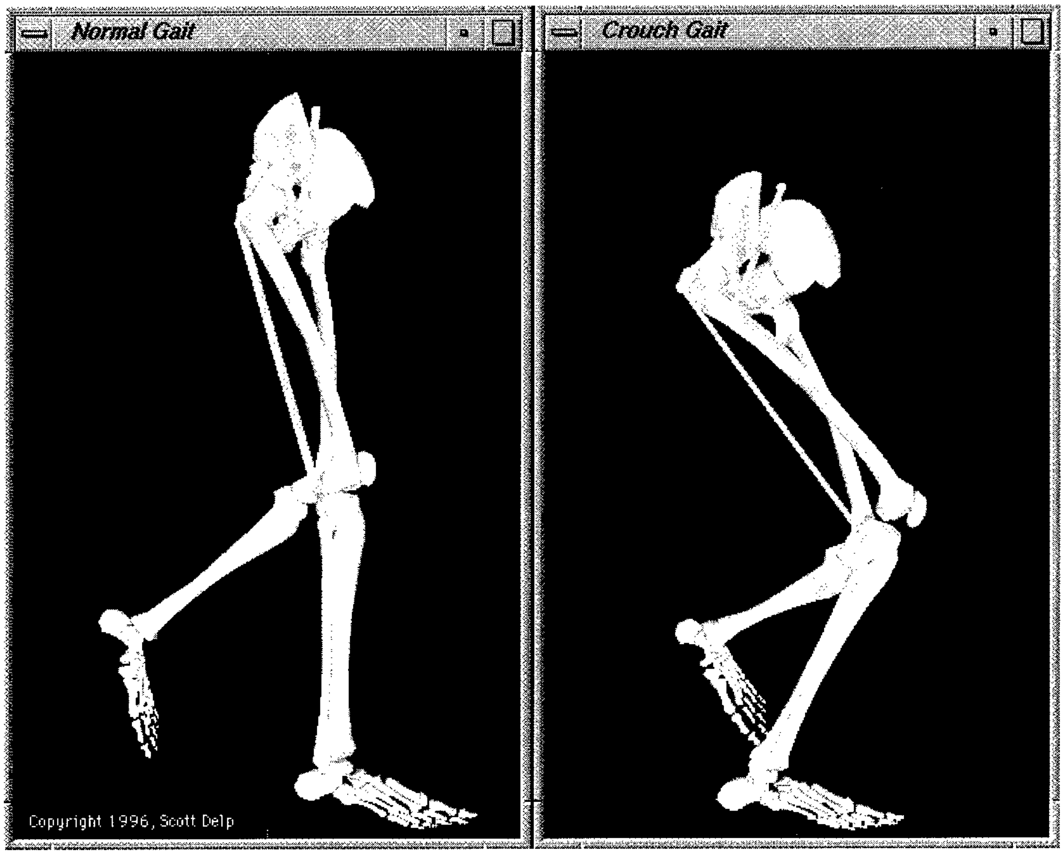


Figure 5-2: A simulator incorporating anatomic and biomechanic models which can be used to explore the functional consequences of a surgical procedure (courtesy of Scott Delp).

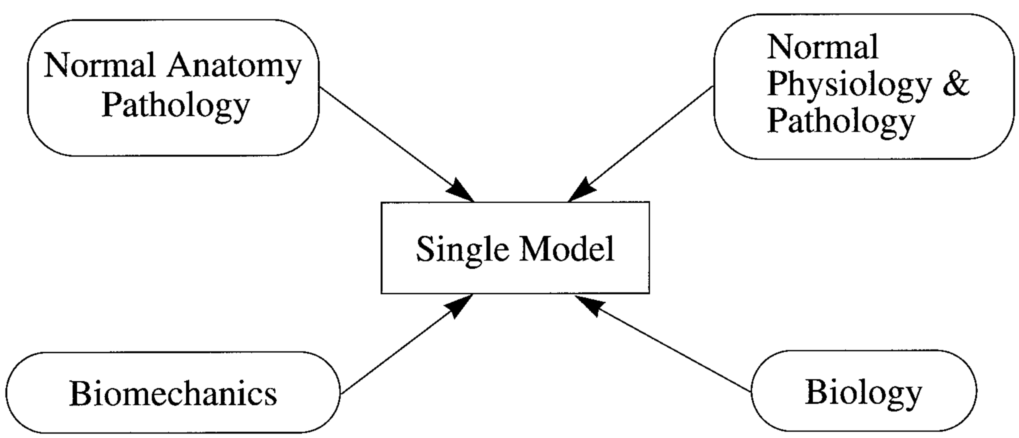


Figure 5-3: Components of a surgical simulation model.

improved visualization during minimally invasive surgery. Simulation also inspires innovation and development of new procedures. In the future, simulators are likely to be used to evaluate and certify clinicians.

5.4 Technical and Research Issues

This section summarizes technical problems which must be solved in order to develop the next generation of surgical simulators.

5.4.1 Development of Effective Modeling Tools

- 3D segmentation - There is a need for more complex tissue characterization and therefore a more complex feature-space. Image-based segmentation should be automated and based upon data from multiple sources. Segmentation can be improved using knowledge bases derived from anatomical and/or functional models.
- 4D modeling - Multidimensional tissue characterization requires multimodality data integration or image fusion. Modeling should include time-dependent changes for the investigation of long-term effects, such as remodeling of joints or tumor growth.
- Scaling - Linear and non-linear scaling methods are necessary to utilize the models in patient care. These methods are used for customizing models for an individual patient. The translation of model parameters and features to the patient will require the development of computational methods and registration techniques.
- Deformations - Predictable and unpredictable deformations in anatomical tissue require the development of various methods. Elastic warping is necessary to match models with a patient's anatomy. More complex deformations may require the utilization of biomechanical properties. It is important to model short *and* long term alterations in morphology in order to assess consequences and outcomes of surgeries.
- Statistical models - It is necessary to collect normative data which describe various parameters of the human body. This should include growth and developmental data and characterization of the aging process. Statistical analysis of surgical results and long term outcomes may provide an important component of optimizing surgical strategies by modeling.

5.4.2 Model Integration

The integration of various models and model-components (i.e., anatomical and functional) into a single model (i.e., virtual human body) is a challenging task which will require an infrastructure for collaboration of a large interdisciplinary team. Integration of the model would be facilitated by image databases, common anatomical modeling software, knowledge of tissue material properties, sharing of key algorithms, and other commonly used utilities. A web page on the Internet would be the logical place to compile this information, along with a list of collaborators, laboratories, and personnel working in this area.

Development of the model should be complemented with the integration of the execution model (i.e., virtual surgery) to obtain the final result of simulation. After scaling and customization, this information can be used for planning and eventually performing the modeled procedure on an individual patient. While training simulators can use generic models of the body, patient-specific models are required for this type of surgical planning.

5.4.3 Enabling Technologies

Inexpensive, robust devices for interaction with surgical simulators are needed. For example, haptic displays, specifically created for medical applications, need to be developed. Stereo visualization systems, on the other hand, will probably be developed for entertainment, scientific visualization, and other applications and might be used in medical applications. In addition, computationally efficient methods for simulating tissue deformation, bleeding, cutting and tearing are needed.

Computer models of the human body developed for entertainment applications are not appropriate for use in scientific analysis and patient care. While simulations developed for entertainment or demonstrations at trade shows may appear to be realistic at a superficial level, they frequently do not account for the underlying mechanics and physiology. This occurs because of the fundamental differences between simulations developed for medicine and those developed for entertainment (Table 5-1).

Table 5-1: Differences between computer graphics in medicine and entertainment

Medical Graphics	Graphics for entertainment
• Physically realistic • Intolerant of artistic license • Interactivity needs flexibility and adaptability • Truth is of absolute importance	• Visually (sensually) realistic • Appreciate and encourage artistic enhancement • Limited paths (i.e., pre-computed actions/scenes) acceptable • Good story is the most important component (i.e., fiction)

Simulations must be tested extensively, both in terms of their accuracy and their efficacy. This involves collection of basic data, tests at each level of simulation, and comparison with clinical results.

5.5 Summary / Recommendations

Our group focused on the coupling of functional and anatomical models. The development of physiologically-based models will allow the creation of more realistic and useful surgical simulations in which the functional consequences of a proposed intervention can be predicted, surgical options can be explored, and results optimized. This new development will have

widespread applications in surgery, medical education, scientific research, patient care, and non-surgical applications. Example applications of simulation in surgery are outlined in Table 5-2.

Table 5-2: Potential Application Areas of Surgical Simulation.

<u>Neurosurgery</u> • Functional neurosurgery	<u>Musculoskeletal Surgery</u> • Limb reconstruction • Joint • Spine • Trauma • Tumor • All	<u>Plastic Surgery</u> • From skeletal structures * Facial simulations * Breast * Donor defects burns
<u>Minimally-Invasive Surgery</u> • Endoscopy • Bronchoscopy • ENT - sinus • Endovascular	<u>Soft-tissue Surgery</u> • Reconstruction of tumor volume and calculation of residual functional capacity for diseases such as liver cancer, lung cancer and respiratory failure	

Section 6 - Teleinterventions

Chaired by: Jon Bowersox and Dietrich Grönemeyer

6.1 Executive Summary

Teleintervention - the application of information-based technologies to deliver procedural health care through an electronic interface. Indirect patient contact is implicit; however, the distance separating patient and physician may be insignificant, or may be great.

The following list represents the major proposed directions for future research initiatives in the area of Teleinterventions:

- The highest priority technical needs are in user interface optimization, system validation, haptic tools, and the development of redundant controllers. Emphasis should also be placed on establishing early relationships with regulatory agencies and national health systems to ensure the timely and appropriate introduction of complex new technologies.
- The greatest user need and value for teleintervention will be in systems that are used locally to enhance dexterity, and reduce the risks, time, and costs associated with complex procedures.

6.2 Introduction, Definitions and Description of Area

The development of information-based technologies has enabled physicians to perform complex therapeutic procedures on patients without directly touching them. Laparoscopic surgery is the most widely applied example of this concept. Surgeons indirectly view intra-abdominal organs through video display interfaces, and tissue manipulation is performed indirectly through long, thin instruments inserted through 5 mm portals. Although highly successful, the performance limitations imposed by minimizing tissue access have created the need for systems that restore natural function and dexterity to surgeons. Furthermore, the realization that therapy could be delivered through indirect visualization and manipulation of tissues stimulated interest in applying computer-assisted medical interventions to locations that were previously inaccessible because of size, minimal entry apertures, distance, or hazardous environments.

Teleintervention is a new term used to describe the application of information-based technologies to deliver procedural-based health care through an electronic interface. Teleintervention is distinct from image-guided therapy in that feedback to and from the clinician is via an electronic interface. In contrast to robotics, direct, human-in-the-loop, operator control of manipulations occurs. Teleintervention, however, may use techniques from image-guided therapy, medical robotics, and surgical simulators as system components. Teleintervention encom-

passes the fields of telepresence surgery, telemanipulation, and teleoperation, in which an operator's hands manipulate remote tissues. It also describes remote teleconsulting, telementoring, and teleproctoring, in which procedures are observed and guided from remote locations (e.g., remote control of cameras, monitoring instruments, and ancillary devices), but in which no actual manipulation of remote tissues is performed.

Teleintervention, as defined here, does not include video teleconferencing for distributed medical education, pre-operative diagnosis, or post-procedural care. Nor does it include current methods of minimally invasive surgery in which an operator's hands contact a patient's tissues through a mechanical linkage (i.e., a surgical instrument). It also does not include telemedicine applications in non-procedural based care, such as diagnostic radiology, cardiology, dermatologic diagnosis, or psychiatry. In teleintervention, the distance from the provider to the patient may be less than a meter when using a micromanipulator system, or as great as several thousand kilometers (or more) when providing teleconsultation to remotely located operating rooms.

Figure 6-1 shows a tele-operated master-slave manipulator with bi-directional force feedback which has been developed for surgical applications. This system has been validated in a number of animal studies.

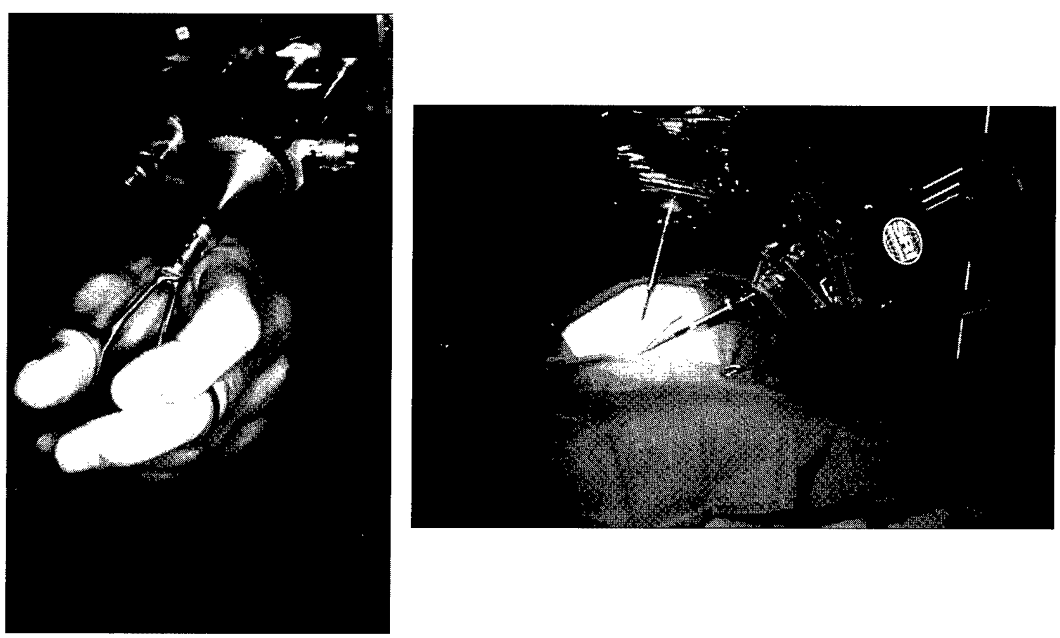


Figure 6-1: Remotely operated master device (left) controlling a tele-operated slave manipulator (right) in a simulated surgical environment (courtesy of Jon Bowersox).

6.3 Review of Current Technology

A number of teleinterventional systems in development are listed in Table 6-1. Active teleintervention has been successfully demonstrated using the SRI Telepresence Surgery System in a variety of pre-clinical studies. Professor Angelini in Rome and Professor Wells in the UK have used a precursor of the MIDSTEP system to demonstrate the feasibility of remote manipulation for a liver biopsy, and will soon begin a multi-institutional study; however, to our knowledge there are no surgical telemanipulator systems currently being used in clinical trials. Passive and assistive surgical teleintervention have been performed on patients at Johns Hopkins University, as described in several recent peer-reviewed publications. Informal clinical studies have been initiated by the U.S. Department of Defense between military surgeons in Bosnia and military medical centers in the U.S. Other active, passive and assistive teleinterventional systems are in various phases of preliminary development in the U.S., Europe, and Japan.

The configuration of teleintervention systems varies based on anticipated needs, but components common to all include a physician, a patient, and an electronic interface linking the patient with the treatment provider (see Figure 6-2). Systems may include robotic manipulators, imaging systems and overlays, and networking/telecommunications components.

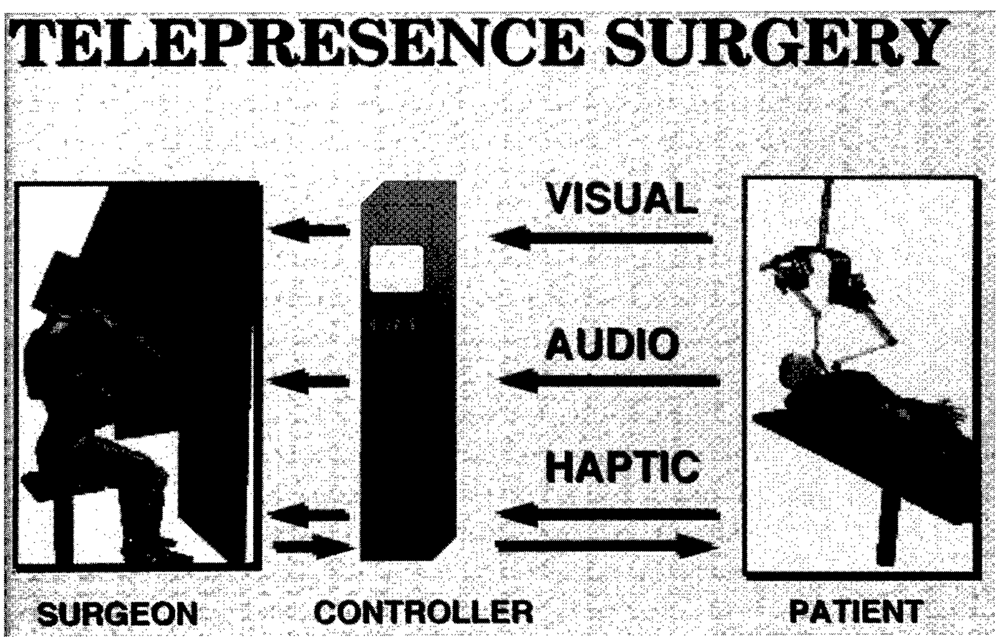


Figure 6-2: Prototypical teleintervention system (courtesy of Jon Bowersox).

Systems currently in development include video and audio displays, haptic interfaces, computers (e.g., controllers, DSP, encryption), telecommunications interfaces, and ancillary components (e.g., monitoring devices, electrocautery and suction controls). Future systems will

Table 6-1: Teleintervention Systems

Product	Classification	Value Added	Development Status	Limitations	Future Needs
SRI Telepresence Surgery System	Telemanipulator	Enable new procedures Increase Access	4DOF Prototype Validated	DOF Latency HCI	Networking HCI Optimization Tactile/Haptic
UVA/VNI Telesurgical Microscope	Telementoring/Teleconsulting	Increase efficiency of specialist surgeon Training	Simulation (Telegrip) Components selected	No Manipulation	Simple Manipulation of OR field
Johns Hopkins/ICE	Telementoring/ Teleconsulting	Training Decrease costs	Clinical trials Incorporating ancillary devices	No manipulation Video display res Latency	Evaluate latency effects HCI Incorporate other devices Teleanesthesia
US DOD	Teleconsulting (Bosnia - US) MIS	Decrease costs (Patients transfer)	System installed COTS	Communication access Not validated with actual cases Improved access scheduling	Network management Support software
US DOD	Teleconsulting (Dentistry)	Access to specialists Decrease evacuation needs (costs)	Intraoral camera available	Same as above	Same as above
European Union (MIDSTEP)	Telemanipulator	Expertise to remote sites (decreased costs)	Prototype 4 sites/2 systems funded	Data security Liability (medico-legal)	HCI optimization Image registration
JPL	Telemanipulator (Micro/ opthalmic)	Improved outcomes	?	?	?
MIT	Same as above				
Tubingen/Karlsruhe	Telemanipulator (MIS)	Enable new procedures	Prototype	No force feedback HCI	HCI Force Feedback

also incorporate image overlay technology from local and networked sources, simulation capabilities, and multi-user environments.

6.4 Technology and Research Issues

6.4.1 Relationship to other RCAMI Application Areas and Enabling Technologies

All of the enabling technologies identified in the pre-workshop report (see Appendix I) have potential application benefits for teleintervention; however, none of the current teleintervention systems evaluated is dependent on these technologies for implementation. One advantage of surgical teleoperators over technologies currently available for image-guided therapy is the ability to precisely manipulate soft tissues. A limitation, however, is the reliance on video as the sole source of information on tissue characteristics. Dynamic overlays of digital imaging data (e.g., MRI, CT) may enable a greater range of teleintervention applications than is currently envisioned. Furthermore, sensory enhancement by fusing multiple sensing sources may compensate for sensory limitations, and allow more intuitive operation of complex systems (i.e., telepresence).

Combining teleintervention systems with surgical simulators may enhance the capability to train for complex, or infrequently performed procedures, and may allow pre-planning, with real-time review during an operative procedure. Likewise, incorporating robots with autonomous or supervisory level control into teleintervention systems may enable operators to gain additional dexterity, decrease time and ancillary labor requirements, and facilitate multitasking.

6.4.2 Technical Limitations and Needs

Several fundamental technical problems and research needs that are key to further development of teleintervention systems were identified.

- Human Computer Interface
  - Ergonomics (instrument design) - available instrumentation has generally been adapted from traditional instruments and other electronic systems, without particular regard to cost or productivity efficiency. Telemanipulators require the development of optimized instrumentation at the master and slave locations. Furthermore, the focus on microinvasive procedures has created a requirement for novel instruments that can be used in conjunction with endoscopic and image-guided techniques. There is a need for MRI-compatible surgical manipulators and instruments.
  - Visual Display (orientation, dynamic variable resolution, stereopsis, frame rate, head-mounted display) - the quality and information requirements for teleintervention applications need to be defined, with the goal of optimizing data needs.

- Audio Input - spatial and qualitative presentation of audio input need to be more fully developed for specific applications.
- Human Performance Engineering - the need exists to define critical cognitive, perceptual, and motor tasks involved in procedural health care, and to develop qualitative and quantitative performance measures that can be used to benchmark application-specific component requirements. Furthermore, performance measures need to be developed and validated for comparing teleintervention systems with each other, and with existing models of health care delivery.

- Communications/Networking
  - Signal Quality
  - Latency
  - Signal Processing - including compression schemes
  - Bandwidth Requirements
  - Traffic Prioritization
  - Controllers
  - Security (encryption)
  - Network Architecture (scaleability, reliability, redundancy)
  - Integration with Hospital Information Systems (electronic patient records, billing, scheduling)
- Imaging
  - Sensory amplification (augmented reality) - includes synthetic data sets from simulators, as well as cue data to define exclusion regions (anatomic danger zones).
  - Image overlays - the incorporation of image registration, and overlay of digital anatomic and physiologic data sets (e.g., duplex ultrasound flow data and images) need to be developed.
- Haptic/Tactile Devices
  - Haptic Interface (tactile sensing, force amplification, latency, fidelity, control systems, DOF) - as a key interface feature of telemanipulators, there is a critical need for both tactile and kinesthetic informational systems.
- System validation (performance measures)
  - Internal (technical evaluation of components)
  - External (application-specific system performance measures)
- Control Systems
  - Redundancy - software and hardware systems for avoiding loss of linkage with remote site, ensuring adequate SNR, emergency protocols (e.g., robotic safety)
  - Real-time Data Integration - from multiplexed sensor sources, databases, system components

- Safety/Standardization
    - Tolerance Limits for Tissue Forces
    - Cross-Industry Analysis of Safety Standards/Tolerances for Automated and Robotic Systems (e.g., aviation industry)
    - Sterilization of highly complex and miniaturized manipulators and system components
    - International specification standards to ensure interconnectibility
- Microsensor/Actuator Development
    - Component miniaturization to incorporate into minimal access interventional systems (minimally invasive surgery, intraluminal and cavitary endoscopy, catheter-based therapeutic systems)

6.5 Existing Deficiencies and Problems

A working relationship needs to be developed between systems developers (academic and industrial) and the FDA. The complexity and novelty of teleintervention solutions to clinical problems, and the potential reliance on robotic and computer systems for therapy necessitate heightened awareness on the part of both developers and regulators. This is distinct from any proposal to form high-level, multi-agency task forces, which may have some value in gaining end user awareness and acceptance. A relationship with the U.S. Health Care Financing Administration (HCFA) and major health care purchasers (e.g., Columbia-HCA) should be established to define buyer needs, limitations, and expectations.

Validation is critical for the development, justification, and clinical acceptance of teleintervention systems, yet no adequate measures of complex medical task performance have been developed. This is a reflection of the high skill level required for many procedures in the surgical specialties, and the multidimensional contributions of cognitive, perceptual, and psychomotor expertise. It will be difficult to develop systems, demonstrate safety, and prove efficacy. Outcomes data will be useful, but the low morbidity and mortality of current therapeutic modalities, and the long duration of well-designed outcome studies will likely require extremely large, multicenter clinical trials to achieve sufficient statistical power. Furthermore, the short product life cycle of technological innovations will jeopardize the value of such studies.

The need exists to perform research in developing validation measures that will be quantitative, reproducible among subjects and systems, and that can be tailored to specific applications. Component (engineering) validation will be needed for intra-system validation, including system integration, networking, control issues, and technical specifications. Systems validation will be needed to assess effectiveness in performing clinical tasks. It is unlikely that

broad application of single measures will result in adequate sensitivity for assessing all requirements.

Patient and operator safety were repeatedly stressed as key concerns that would hinder system acceptance by users (physicians and patients), and by regulatory agencies. Although commercial development will provide some of the impetus for redundant control systems, basic technical issues that need to be addressed include defining tolerable force limits on human tissues, developing software to ensure redundancy for local manipulator systems, and data integrity, security, and redundancy for networked transmissions. Sterilization issues (requirements, techniques) for complex, reusable manipulators and instrumentation also need to be defined. Other existing deficiencies are in international standards for teleintervention systems specifications and description. Non-technical issues raised include medicolegal liability, patient acceptance, and the ethics of health care delivery using an electronic interface.

6.6 Summary / Recommendations

The benefits of local teleintervention systems will be enabling completely new procedures that cannot be performed now because of limitations in dexterity, access (minimally invasive, microscopic, intraluminal endoscopy), or complexity. Intra-hospital systems will also be used for skill acquisition and retention (training), using a simulated environment. These systems are likely to be implemented in low volume, at tertiary and quaternary medical centers.

Networked, or remote, teleintervention systems will find the greatest use in primary care, community settings. They will be used to increase patient access to procedures performed locally (e.g., enabling general surgeons to perform standard urologic or otolaryngologic procedures under the mentoring of a remotely located specialist), optimize the distribution of health care resources, and enhance training.

An additional application area meriting evaluation is in delivering anesthesia care remotely. Anesthesia providers currently interact with patients through electronic and mechanical interfaces, thus making the transition to teleanesthesia care relatively easy. The potential to provide closer supervision of nurse anesthetists and physicians in graduate medical education, and the ability to observe and mentor less experienced anesthesia providers through rare or complex cases performed at a community hospital are direct potential benefits of teleinterventional technology. Directly achievable cost savings and improved patient outcomes are possible through this application.

Appendix A Workshop Participants

Workshop participant breakdown:

Table A-1: Workshop Statistics (Participants Only)

Participating Countries	M.D.	Ph.D.	Other	Total
United States	8	10	2	20
Germany	2	2		4
United Kingdom	6	8		14
Japan	5	3		8
France		3		3
Switzerland		1		1
Italy	1	1		2
Total	22	28	2	52

Workshop Organizers

Anthony DiGioia, M.D. — Shadyside Hospital / Carnegie Mellon University
digioia@cs.cmu.edu

Takeo Kanade, Ph.D. — Carnegie Mellon University
kanade@cs.cmu.edu

Peter N. T. Wells, Ph.D. — Bristol General Hospital
peter.wells@bristol.ac.uk

Workshop Associates

Frederick M. Morgan — Carnegie Mellon University
fxm@ri.cmu.edu

David A. Simon — Shadyside Hospital / Carnegie Mellon University
das@ri.cmu.edu

Executive Oversight Committee

Licinio Angelini, M.D. — Universita degli Studi di Roma

Nicholas Ayache, Ph.D. — INRIA
nicholas.ayache@inria.fr

Philippe Cinquin, M.D. — Institut Albert Bonnoit
philippe.cinquin@image.fr

Paolo Dario, Ph.D. — ARTS Lab Scuola Superiore
dario@sssup1.sssup.it

Brian Davies, Ph.D. — Imperial College
b.davies@ic.ac.uk

Takeyoshi Dohi, Ph.D. *dohi@miki.pe.u-tokyo.ac.jp*	The University of Tokyo
Toyomi Fujino, M.D. *tfujino@sfc.keio.ac.jp*	Keio University Hospital
Dietrich Grönemeyer, M.D. *groesei@uni-wh.de*	Mulheimer Radiologie Institut
Heinz Lemke, Ph.D. *hul@cs.tu-berlin.de*	Technische Universitat Berlin
Lutz-Peter Nolte, Ph.D. *nolte@mem.unibe.ch*	University of Bern
Russell Taylor, Ph.D. *rht@cs.jhu.edu*	Johns Hopkins University
Eiji Watanabe, Ph.D. *I01600@sinet.ad.jp*	Tokyo Metropolitan Police Hospital
Peter N. T. Wells, Ph.D. *peter.wells@bristol.ac.uk*	Bristol General Hospital

Teleinterventions Working Group

Co-Chairs:

Jon C. Bowersox, M.D. *jon_bowersox@qm.sri.com*	SRI International
Dietrich Grönemeyer, M.D. *groesei@uni-wh.de*	Mulheimer Radiologie Institut

Keynote:

Philip Green, *philip_green@qm.sri.com*	Telesurgical Corporation

Participants:

Licinio Angelini, M.D.	Universita degli Studi di Roma
Major Conrad Clyburn *clyburn@matmo.army.mil*	United States Army
Gilbert B. Devey *gdevey@nsf.gov*	National Science Foundation
J. Hunter Downs, Ph.D. *downs@virginia.edu*	Virginia Neurological Institute
Michael Halliwell, Ph.D.	University of Bristol Healthcare Trust
Louis Kavoussi, M.D. *pooks@welchlink.welch.jhu.edu*	Johns Hopkins Medical Institutions
Heinz U. Lemke, Ph.D. *hul@cs.tu-berlin.de*	Technische Universitat Berlin
H. L. Young, M.D.	Welsh Medical Technical Forum U.K.

Robotics/Manipulators

Co-Chairs:

David Stulberg, M.D.	Northwestern Medical Faculty
jointsurg@nwu.edu	
Russell Taylor, Ph.D.	Johns Hopkins University
rht@cs.jhu.edu	

Keynote:

Russell Taylor, Ph.D.	Johns Hopkins University
rht@cs.jhu.edu	

Participants:

Peter N. Brett, Ph.D.	AMARC, University of Bristol
Norman Caplan	National Science Foundation
ncaplan@note.nsf.gov	
Paolo Dario, Ph.D.	ARTS Lab Scuola Superiore
dario@sssup1.sssup.it	
Brian Davies, Ph.D.	Imperial College
b.davies@ic.ac.uk)	
Herve Druais, Ph.D.	DeeMed International
Patrick Finlay, Ph.D.	Armstrong Projects Limited
pfinlay@armstrong.co.uk	
Robert Howe, Ph.D.	Harvard University
howe@das.harvard.edu	
David Sandeman, M.D.	Frenchay Hospital
Anthony Timoney, M.D.	Southmead Hospital
Mark A. Tooley, Ph.D.	Bristol General Hospital
Peter N. T. Wells, Ph.D.	Bristol General Hospital
peter.wells@bristol.ac.uk	
John Wickham, M.D.	Guys Hospital

Surgical Simulators

Co-Chairs:

Scott L. Delp, Ph.D.	Northwestern University
delp@casbah.acns.nwu.edu	
Ferenc A. Jolesz, M.D.	Brigham and Women's Hospital
jolesz@bwh.harvard.edu	

Keynote:

Edmund Y.S. Chao, Ph.D.	Johns Hopkins School of Medicine
rkrasner@eagle.gsh.jhu.edu	

Participants:

Herve Delingette, Ph.D.	INRIA, Project EPIDAURE
delingette@sophia.inria.fr	

Toyomi Fujino, M.D. *tfujino@sfc.keio.ac.jp*	Keio University Hospital
Sarah Gibson, Ph.D. *gibson@merl.com*	Mitsubishi Electric
Branislav Jaramaz, Ph.D. *branko@cs.cmu.edu*	Shadyside Hospital
Takeo Kanade, Ph.D. *kanade@cs.cmu.edu*	Carnegie Mellon University
Masahiro Kobayashi, M.D. *kkbb@sfc.keio.ac.jp*	Keio University School of Medicine
Zygmund Krukowski, M.D.	Aberdeen Royal Infirmary
A. D. Linney, Ph.D. *alf@medphys.ucl.ac.uk*	University College London
Jeffry L. Marsh, M.D. *marsh@mirlink.wustl.edu*	St. Louis Children's Hospital
Hiromu Nishitani, M.D. *hiro@clin.med.tokushima-u.ac.jp*	Tokushima University Hospital
Dennis Robinson, Ph.D.	Engineering and Physical Sciences Research Council
Joseph Rosen, M.D. *joseph.rosen@hitchcock.org*	Dartmouth-Hitchcock Medical Center
Faina Shtern, M.D. *faina_shtern@nih.gov*	National Cancer Institute

Image Guided Procedures

Co-Chairs:

Richard D. Bucholz, M.D. *bucholz@musu2.slu.edu*	St. Louis University School of Medicine
Lutz-Peter Nolte, Ph.D. *nolte@mem.unibe.ch*	M. E. Muller Institute, University of Bern

Keynote:

Stephane Lavallee, Ph.D. *stephane.lavallee@imag.fr*	TIMC Lab, IAB Faculte de Medicine

Participants:

James Anderson, Ph.D. *jander@rad.jhu.edu*	Johns Hopkins Medical Institutions
R. N. Baird, M.D.	Bristol General Hospital
Alan C. F. Colchester, M.D. *a.colchester@umds.ac.uk*	Kent Inst. of Med. & Health Sciences
Anthony M. DiGioia, M.D. *digioia@cs.cmu.edu*	Shadyside Hospital / Carnegie Mellon University
James S. Duncan, Ph.D. *duncan@noodle.med.yale.edu*	Yale University
Eric Grimson, Ph.D. *welg@ai.mit.edu*	Massachusetts Institute of Technology

David J. Hawkes, Ph.D. *d.hawkes@umds.ac.uk*	UMDS, Guys Hospital
Tomohiko Kihara, Ph.D. *kihara@mel.nasu.toshiba.co.jp*	Toshiba Corporation
Michael Kuhn *kuhn@pfh.research.philips.com*	Philips Forschungslaboratorien
Jochen Kusch	Siemens Erlangen
Helen Lovell, Ph.D. *helen.lovell@epsrc.ac.uk*	Engineering and Physical Sciences Research Council
Ralph Mösges, M.D. *hno2@alpha.imib.rwth-aachen.de*	Aachen Hospital
Sally Norton, M.D.	Bristol Royal Infirmary
Klaus Radermacher, Ph.D. *radermacher@hia.rwth-aachen.de*	Aachen University of Technology
Michael R. Rees, M.D.	University of Bristol
David A. Simon *das@ri.cmu.edu*	Shadyside Hospital / Carnegie Mellon University
Jun-Ichiro Toriwaki, Ph.D. *toriwaki@nuie.nayoga-u.ac.jp*	Nagoya University
Michael W. Vannier, M.D. *mvannier@brian.wustl.edu*	Washington University
Kirby G. Vosburgh, Ph.D. *vosburgh@crd.ge.com*	General Electric Company
Eiji Watanabe, M.D., Ph.D. *I01600@sinet.ad.jp*	Tokyo Metropolitan Police Hospital

Appendix B Image Guided Therapy Keynote

Keynote Address given by: Stephane Lavallee

		Status		
		Now in products	Now in labs	Future trends
Issue	Medical Information	Pre-Op CT & MR open MRI, endoscopy	All images and atlases	Miniaturized sensors
	3-D Localizer	• Cameras and LEDs • Mechanical arms • Magnetic sensors	Passive systems (optical)	Passive, small, cheap, accurate, transparent
	Registration	• Point matching (External /anatomical landmarks) • Frames	Anatomy-based registration (pointers, range sensors, X-ray, 2.5D US, templates), video images	Fully automated, easy, fast and robust
	Segmentation	• Thresholding and manual editing	• Deformable models • Statistical methods	• Fully automated • Fast and accurate
	Other Non-Medical Information		• Range sensor • Force and tactile sensor • Motion analysis	• Physical properties (impedance, pressure, etc.)
	Visualization	• “Real-Time” slicer • Standard screens • Video overlay	• Helmets	• Computer power up • Flat screens

		Status		
		Now in products	Now in labs	Future trends
Issue	Hardware / man- machine interface	• Mouse, keyboard, pedal switch • Technical person!	• Use of localizer • Force-feedback arms • Simple tool like templates	• More automated procedures
	Surgical Planning - Interactive	• Stereolithography • Basic visualization tools	• Simulation with visual & force feedback	• Realism
	Surgical planning - optimization	Models	Models	Models (Short term and long term morphological and functional consequences)
	Ergonomics	OK for the "technical" surgeon!	Some work	Transparent for the non-technical surgeon
	Cost	Too much expense vs. benefits and versatility	Clinical benefits increasing	• Standardization • Modular architecture • Multi-application • Cost reduction?
	Clinical Validation	+	++	+++++

Appendix C Robotics Keynote

Keynote Address given by: Russell H. Taylor

Medical Robotics
and Computer-Assisted Surgery

Russell H. Taylor
Department of Computer Science
The Johns Hopkins University

Robot ≠ Surgeon

So what is "Medical Robotics"?

Application of "robotic" technologies
- –Sensing
- –Manipulation
- –Modelling and Geometric Analysis
- –Human-Machine Interfaces

to enhance human clinicians' ability to plan and carry out interventional procedures

Robot = Surgical Tool

Robot + Human > Unaided Human

A plan must be <u>executable</u>

–

if it is to be <u>useful</u>

Taxonomies

- By Technology/Research Area
- By Application
- By Class of System

Technology/Research Area

- **Image Processing**
  - Acquisition
  - Segmentation
  - Registration
  - *Visualization*
- **Analysis**
  - Modelling
  - Simulation
  - Optimization
  - *Visualization*

Technology/Research Area

- **Robotics**
  - Sensing
  - Manipulation
  - Human-machine interfaces, including *visualization*
- **Systems**
  - Safety
  - Robustness
  - Information management and communication, including *visualization*

Application Areas

- Neurosurgery
- Orthopaedics
- Opthomology
- General Surgery
- Urology
- Craniofacial
- Dentistry
- Microvascular
- Oncology
- Podiatry
- Otolaryngology
- *etc.*

Considerations

Factors to consider

- Safety
- Efficacy
- Utility
- Market
- System cost
- Regulatory Issues
- Enabler

Points of leverage

- New Procedures
- Consistency
- Time
- Cost
- Complication rates
- Healing times

Points of Leverage

How can the inequality be satisfied?

- Ability to do it at all
- Consistency
- Time
- Cost
- Safety to clinicians
- Safety to patients
- Healing times
- *etc.*

The Roles Systems Play

- Navigational Aids
- "Intern Replacements"
- Telesurgical Systems
- Precise Positioning Systems
- Precise Path Systems

Navigational Aids

- Goal is positional information support
- Often called "CAS" systems
- Usually consist of
  - localizer
  - registration
  - display

"Intern Replacements"

- Retractors
- Instrument Clamps
- Limb Positioning Systems
- Laparoscopic Camera Holding Systems

Telesurgical Systems

- Surgeon controls "master"
- "Slave" robot follows motions
- But ... can be made much smarter

- Local Assistive Surgery
- Remote Surgery

Remote Surgery

Operate at a distance
- Military/disaster applications
- Remote health care delivery

Main Challenges:
- Time Delay
- "Presence"

Local Assistive Surgery

Use system to extend surgeon's capability
- Laparoscopic surgery
- Eye/microsurgery

Main Challenges:
- Surgeon interface
- Functions

Steady Hand Manipulation

- Hands on guiding with
  - actively enforced constraints
  - shared autonomy
- Typical applications:
  - Orthopaedics
  - Neurosurgery
  - Microsurgery
- E.g., Davies, Taylor, ...

Precise Positioning Systems

- Goal is accurate positional alignment
- Provide manipulation assistance
  - Passive - *e.g., osteotomies*
  - Semi-active - *e.g., point biopsies*
  - Active - *e.g., pattern therapy*

Localized Therapy Delivery

Goal:

- Optimized planning of therapy pattern using 3D images
- Robotically assisted delivery using "light-weight" intraoperative images

Localized Therapy Delivery

Technical challenges:

- Proof of modality
- Image Segmentation
- Image/robot registration
- Patient/organ motion & deformation

LIVER CANCER

- Hepatomas
  - 10,000 cases/year, 25% operable
- Metastatic Colon Cancer
  - 25,000 cases/year, 30% operable
- Average surgery charges at JHU Hospital
  - \$22,000/case, 10 day hospital stay

Goal: Percutaneous Treatment

- Significantly increase indication rate
  - Condition of patient
  - Relative benefit
- Significantly decrease cost
  - Perhaps \$6,000-\$7,000/case
- Significantly reduce hospital stay
  - Perhaps 1-3 days

Percutaneous Kidney Puncture

- Goal is to place needle into the filling system of the kidney
- Initial experiments:
  - Biplanar guidance, LARS robot
- Eventual system
  - Single C-Arm, New Robot

Precise Path Systems

- Goal is accurate following of predefined path.
- E.g.,
  - Orthopaedics
  - Radiation beam therapy
- Systems can be both active and passive

Robodoc

- **IBM Research + UC Davis**
  - Exploratory work (1986-1988)
  - Prototype system (1989-1990)
  - Veterinary trial (1990)
- **Integrated Surgical Systems**
  - Phase 1 trial (11/92-3/93)
  - Phase 2 trial (10/93-...)
  - Commercial deployment in Europe (1995 -...)

Hap's four laws of robotics

- The surgeon is the boss
- Never run amok
- Never push too hard
- Stay where you are supposed to be

Insertability Analysis

- Goal is determining whether implant can be inserted into prepared hole.
- Approach
  - Simulate 6 DOF extraction & reverse
  - Input = CAD files
  - Output = Path or "stuck" configuration

Joskowicz & Taylor (1994, 1995)

Revision Hip Surgery

Joint Activity:

- Integrated Surgical Systems
- IBM Research
- Johns Hopkins University

Demographics

- **Increasingly common**
  - 23,000/year (US, 1992)
  - 10% annual growth
- **Expensive**
  - Average cost = $24,000, 11 day hospital stay
- **Error Prone**
  - 18% fractures
  - 10% cortical penetration

Revision THR Issues

- **Planning**
  - CT Reconstruction artifacts
  - Use of (imperfectly registered) x-rays
  - Segmentation
  - Contingency planning

Revision THR Issues

- **Execution**
  - Registration
  - Intraoperative plan verification
  - Intraoperative plan modification
  - Human-machine interaction

Wither are we tending?

- "Medical Robots" are still surgical *tools* intended to be used as part of surgical *systems*.
- Systems that exploit *integration* of images, models, plans, and manipulation will become more prevelant.
- Systems will be both *subjects* of research and *enablers* for research.

How to get there

- Pick good problems
  - Clinical importance and technical interest
- Invest heavily in team building
  - Clinicians and Engineers
- Rapid iteration with careful evaluation
- Sharing of Lessons

Appendix D Surgical Simulator and Virtual Reality Modeling in Orthopaedics

Keynote Address given by: Edmund Y.S. Chao

D.1 Introduction

I truly appreciate the honor of being invited by this very distinguished group to discuss one of the major topics of this workshop, the "**Surgical Simulator**". With the amount of time given to me, I intend to comment on other sub-topics, hoping to set the stage and provide examples for our deliberations during the next 2 1/2 days. Several important issues, both technical and non-technical, will be discussed. I would like to add to the list provided by the workshop chairman relating to the recognition of new engineering technology transfer to medicine and surgery, and hopefully, to share the spotlight and funding currently occupied by the dominating fields of molecular biology and gene manipulation. It is interesting to note that the application of biology and physiology principles to the vast field of engineering technology, under the discipline described as "**Bionics**", has long been recognized as the impetus for advancements in our engineering sciences and industry. Therefore, bioengineering provides a two-way street where technology cross-feeds both the medical and the engineering fields. However, it is important to emphasize the distinct difference between the new technologies proposed for medical education, research, and services (surgical simulation, virtual reality modeling, image-guided procedures, etc.) and those used in multi-media applications, entertainment, advertising, and courtroom deliberation.

D.2 The Scope of Surgical Simulator in Orthopaedics

This workshop deals with four topics: 1) Surgical Simulators; 2) Image-Guided Procedures; 3) Robotics/Manipulators; and 4) Tele-Intervention. The surgical simulator relies upon Virtual Reality models and physical models which can be used for pre-treatment planning, medical research and education. Supplementary to its clinical applications, Virtual Reality models can yield biomechanical information unavailable from *in vivo* or *in vitro* studies. Realistic physiological movement and joint reaction forces in the musculoskeletal systems can be determined using Virtual Reality biomechanical models and validated through mechanical testing on cadaver specimens.

The motivation for developing the concept of a surgical simulator in orthopaedic surgery was stemmed from the treatment of musculoskeletal neoplasm. When treating a bone or soft tissue tumor, a special PET scan is often used to characterize and localize the lesion. After pin-point-

ing the precise margin of the lesion, the surgeons can use computer-guided biopsy and treat the affected region with imaging-guided procedures such as focalized radio-therapy for tumor control. Following medical management, surgical resection is often indicated. When performing a resection, the boundary of the lesion must be safely contained by a layer of normal tissue, thus necessitating removal of a large volume of bone and soft tissue, followed by major reconstruction. After such a radical resection, surgical reconstruction can be planned using computer-aided implant design and image-guided implantation. Finally, optimal and safe rehabilitation program can be planned using a Virtual Reality model of the reconstructed region in order to regain functional use of the salvaged limb and joint system. Such an integrated application of the new engineering technology helps to set the stage for the present discussion on surgical simulation and the use of virtual reality modeling in orthopaedics. It also exemplifies the value of such technology as applied to medical education, surgical training, basic research and clinical patient care covering all aspects of orthopaedics.

D.3 Role of VR Modeling (Virtual Human) in Surgical Simulation

The concept of robotics and its medical application played an important role in the present workshop and it has specific implication to the development of surgical simulation. In this respect, the entertainment world shared the initial stimulation. The underlying plot of the movie, **Jurassic Park**, was medical and biological based, an interesting application of the chaotic theory in genetic mutation. More importantly, it was the remarkable Virtual Reality modeling and mechanical simulation of the dinosaurs that gave a lifelike effect through computer graphics and robotic manipulation. Such computer and engineering marvels provided the impetus to the development of the **Virtual Human** model. The virtual human is a programmable human musculoskeletal system on a computer workstation that can give us the dynamic responses of the system under applied loads and measured kinematics. The associated biomechanical information related to muscle forces, stresses in the bone and joint under simulated physiological function not only can be quantitated but also displayed in an animated fashion together with the graphic model. Surgical simulation as well as the remaining topics of this workshop will require the virtual human model to facilitate their utility.

What are the advantages that a surgical simulator utilizing virtual reality modeling can provide? First of all, a virtual reality model offers a risk-free environment. It is a potential hazard to use specimens which have not been screened for Aids and Hepatitis. Obviously, the appearance and odor of the specimen will not be attractive to work with for an extended period of time. In addition, it will deteriorate and become spoiled, thus losing its anatomical composition and physiological properties. Even using the best and most sophisticated mechanical simulators, not all physiological functions can be reproduced on cadaver specimens. In contrast, the virtual reality biomechanical models, after proper validation, can provide infinite combinations of normal and pathological conditions to study their effects on system responses and to predict therapeutic outcomes. Of course it will be difficult to simulate blood, haptic and

sensory feedback. These are not mandatory in all surgical simulators to provide practical and essential applications.

The flight and vehicular simulators are the best engineering examples which have been in extensive use during the last two decades. They serve as standard test-beds or virtual laboratories for personnel training, equipment design and testing, accident simulation and prevention. The same simulators could be created to study human musculoskeletal system function, disease progression, and surgical reconstruction entirely on computer models -- a basic motivation to develop the **Virtual Human**. Such a model, however, must satisfy certain basic requirements in order to be used as a viable surgical simulator. It must provide anatomic accuracy and visual fidelity. In certain models, organ and tissue properties must be provided. For cardiovascular and pulmonary function, blood flow and air exchange in the heart and lungs must be visualized. In the musculoskeletal system, biomechanical analysis capability should be included to show how the system moves, what the internal forces are, and how they interact. Tactile feedback can be useful through instrument design and virtual environment creation.

D.4 Development of the Virtual Human Model

Can a Virtual Human model be developed to study the normal and abnormal functions of the musculoskeletal joint system? The answer is definitely yes! We have generated a computer graphic model of the human musculoskeletal system that can perform dynamic sporting activities such as baseball pitching. From such a model, one can study the joint motion and forces involving the shoulder, and proceed to investigate the effect of fatigue on muscle control as a potential source of ligamentous injury. Many other applications to be described later will clearly demonstrate the unlimited potential of such technology.

To accomplish the required simulation goals, a three-dimensional database for visualization of human anatomy and physiology was initiated through the Advanced Technology Program funding awarded from the Commerce Department four years ago. The Virtual Human modeling work and its medical application were regarded as high-risk technology and thus rendered special support. Fresh cadaver bodies were obtained for MRI and CT scans at refined increments. These bodies were later frozen and embedded in foam material for cryo-sectioning at 2-5 mm intervals. Based on the digital images, bone and muscle boundaries were obtained to reconstruct the three-dimensional models using patched C-spline functions. When the boundaries of the vital structures and tissues such as nerves and vessels were not clear enough, stained sections were used to distinguish the margins with the aid of anatomy text books. In many aspects, this effort was similar to the "visible human" program sponsored by the National Library of Medicine. However, the major difference between our "Virtual Human" and the "Visible Human" database is that the former is an analytically based model which can

provide biomechanical analysis with results animated to emulate musculoskeletal system function with remarkable accuracy and flexibility.

The virtual human model, or the Virtual Biomechanical Model, has many unique features and capabilities. This model is visible, anatomic, and interactive. Muscle orientation, joint geometry and material properties can be changed to simulate a wide variety of pathological conditions. Static and dynamic analyses can then be performed to examine their effects on joint function. Most importantly, joint contact pressure, ligamentous tension and the stresses in the bone can all be determined using Finite Element Analysis software or the simplified Rigid Body Spring Modeling (Discrete Element Analysis) technique. Hence, this model is not only anatomic but also computational (Figure D-1). With kinematics input, measured external loading and estimated inertial properties of the body segments, the virtual human model can be made to perform dynamic activities with full visualization capability. Its interactive nature provides the basic requirement for a surgical simulator to fulfill its utility in medical education, research and patient care.

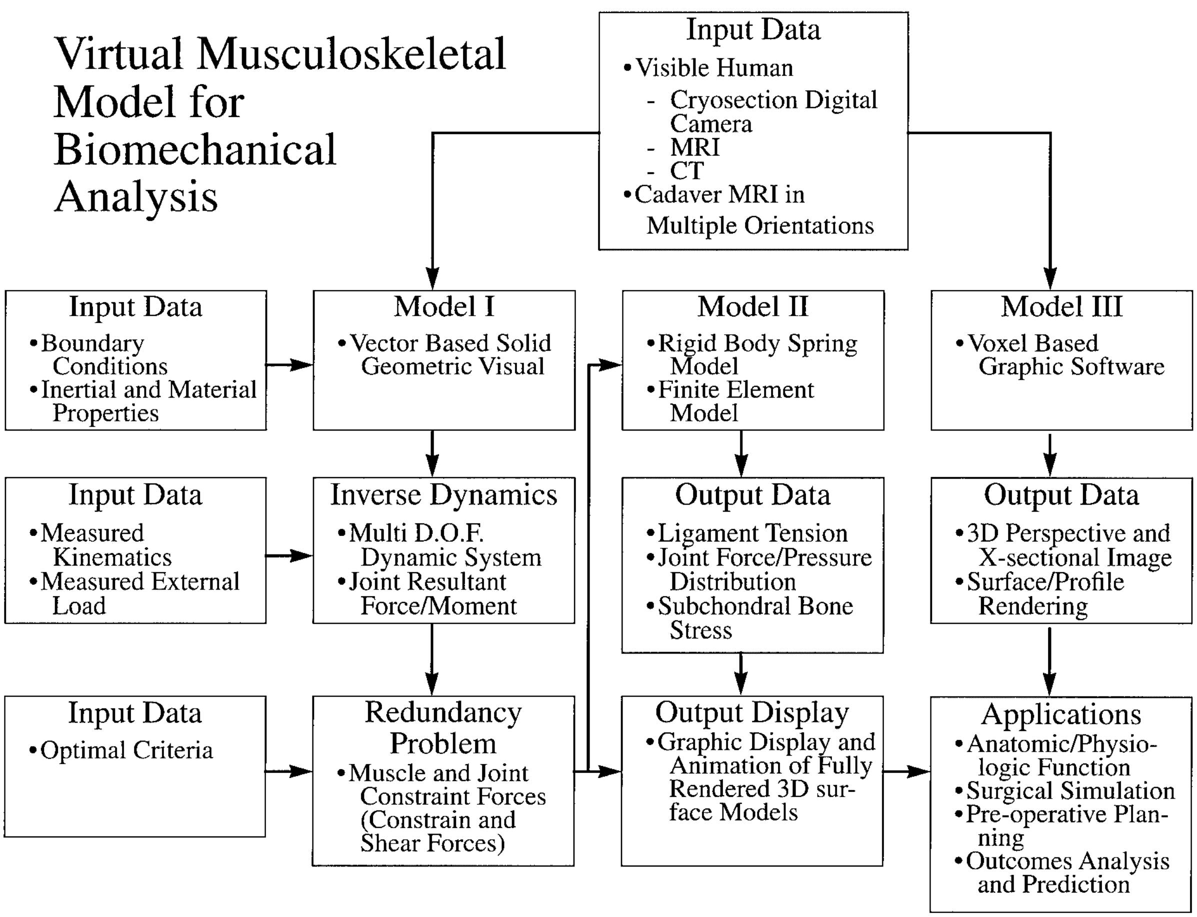


Figure D-1: The flow-chart diagram for the Virtual Musculoskeletal model for biomechanical analysis.

D.5 Application of Virtual Reality Modeling

Surgical simulation includes three fundamental areas. The first area involves a surgery-based simulation model to be used for pre-operative planning, intra-operative guidance and post-operative outcome assessment. The second area of simulation is to provide an analytical model for biomechanical analyses of the musculoskeletal system in action, a virtual dynamic testing laboratory. Finally, a surgical simulator using both graphical and physical models with haptic and sensory feedback can provide surgical training and demonstration. One of the examples of the last simulation application is in the field of arthroscopic surgery. Using simulated fiber optics instruments, the surgeon or trainee can look through the scope to locate surgical instruments in reference to vital tissues in the joint space and perform surgery under direct-image guidance.

Another example is a three-dimensional bony structure of the pelvis providing detailed anatomy of the SI joint, pubic symphysis, the hip joints and all the essential soft tissues defined in geometric and physical terms. Free-body analysis in order to produce biomechanical results based on applied forces and measured kinematic input data can be carried out. With this unique capacity, one can investigate pelvic instability, hip joint force transmission, and the effect of fracture fixation or pelvic/acetabular osteotomies on the functional responses of the hip joint. In addition, dynamic analysis of the hip joint during gait can be studied under simulation of abnormal muscle function. This model can be used to estimate the joint range of motion during activities of daily living and under various reconstructive procedures, including total joint replacement. With the help of FE analysis and the Rigid Body Spring Modeling technique, three-dimensional stresses on the joint surface and in the stem, cement and bone cortex can all be calculated as a function of loading cycle during gait. Such a model also offers an objective assessment of rehabilitation programs designed for the related joints to assure efficacy and safety.

The same technology presented in this paper can be applied equally well in non-surgical disciplines. The virtual reality modeling technique is particularly attractive in focalized radiation for the control of cancer. An individual patient's lesion location can be scaled on the existing graphic model to plan the radiation program. Computer-aided rehabilitation (CAR) and the design and application of rehabilitation robots are additional examples. Through visual feedback, exercise can be modeled and analyzed to improve rehabilitation safety and effectiveness tailored to each patient's needs and limitation. The computer model of the exercised limb and joint system displayed on the monitor provides quantitative feedback for the patient to pace their effort level in order to achieve the therapeutic goal.

D.6 Discussion

To achieve the aforementioned goals for surgical simulation using virtual reality biomechanical models, certain technical obstacles must be overcome. The virtual reality model itself has to be validated. The simulator's reliability and consistency must be established and we must be able to determine the ideal type of simulator for specific applications in surgical training, basic research and in clinical patient care. In addition, the simulator must be safe, relevant, practical and most importantly, affordable. For preoperative planning purposes, the musculoskeletal model must be compared with an actual anatomic specimen tested on mechanical simulators under similar loading conditions. Model validation is the essential prerequisite for such technology to gain general acceptance in the medical community. Of course, there is no substitute for clinical trials in order to establish the credibility and accountability before widespread clinical application.

With the enormous technology available to us today, computer-assisted surgery, tele-medicine, and tele-surgery are not only possible, they have already been implemented at several institutions for research and demonstration purposes. Surgery can be performed at a remote site under tele-guidance and tele-intervention. Practicing tele-medicine will require careful implementation of software programs incorporating artificial intelligence to facilitate decision making proficiency. Additional factors involving personnel experience, training background, environmental constraints, the extent of disease or traumatic injury, the availability of facilities and instruments, and the data/image communication network efficiency are the key determinants for their successful and practical utilization. Until these technical barriers are sufficiently resolved, much of the advanced medical applications discussed here will remain academic.

Robotics and computer-assisted medical intervention require certain enabling technologies. Much of these enabling technologies are readily available, but not appreciated by the medical professionals and the policy making administrators. It is up to us to transfer these available technologies from engineering and physical science domains into medicine and surgery while attempting to convince the funding agencies and foundations of the enormous potential of these new developments. A combination of a virtual reality computer model and a physical model, a form of **Hybrid Reality**, can be utilized to overcome the inherent skepticism among physicians and basic scientists. We have to take advantage of the innovative imaging technology developed for the mass media and the entertainment industry to provide a more vivid graphic model and the means to manipulate and scale the model in order to adopt a patient's specific conditions to the existing virtual model for the required analyses and visualization. Although these are formidable tasks, these challenges can be met by well-trained engineers with dedicated effort towards medicine and surgery, as they have done so for many medical and non-medical fields in the past. With appropriate funding, it will only be a matter of time before such technology seeks its proper place in the vast medical world.

Engineering technology has not been blamed for today's escalating medical costs. However, unwise or careless application of the technology discussed herewith may affect the remarkable reputation established by the bioengineers through their enormous contributions to the medical field during the long and productive era covering the last three decades. Our optimal goal is to ensure that modern technology and medical research accomplishments can be cost effectively applied in today's managed care environment through engineering.

Finally, when discussing the practical nature of RCAMI, the non-technical issues involved must also be carefully elucidated. If such technology is contemplated for clinical application, it must be assessed and approved by the consumers, i.e., the patients. Its validity should not be evaluated by anyone directly involved in the development or transfer of such technology. The balance between cost and benefit must be carefully weighed. Acceptance, not only by the medical professionals and the health care management but also by the lay people, will provide the required seal of approval. The FDA accreditation and the annoying liability issue are the additional concerns. Until then, the entire field related to RCAMI will remain in the academic domain. Even so, such development does represent a landmark advancement in fostering engineering technology in medical research and education. This will be the most powerful tool for all human health related endeavors for the next century.

Appendix E Teleinterventions Keynote

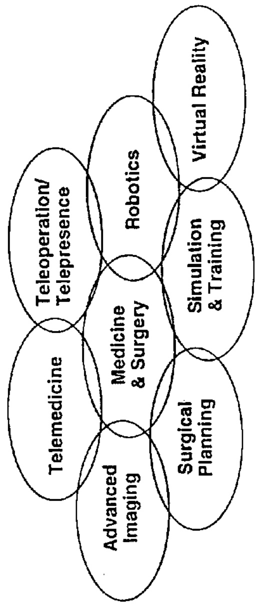
Keynote Address given by: Philip Green

Telesurgery

Philip S. Green
Telesurgical Corporation
Palo Alto, California

Telesurgical Corporation

Converging Technologies That Will Change the Practice of Medicine and Surgery



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Telesurgical Technology— *Two Distinctly Different Uses*

- *Remote Surgery*—Hands-on surgery from a distant site.
- *Enhanced Dexterity*—Improved precision in microsurgery and endosurgery.

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A Few Definitions

Robotics
— Automatic control of a positioning and manipulating device.

Teleoperation
— Remote control of a "slave" manipulator by a human operator, making like movements of a hand-controlled "master" manipulator.

Telepresence
— Teleoperation, with the illusion that the remote worksite is actually in front of the operator, who, in effect, reaches into it to work.

Virtual Reality
—Full visual and auditory immersion in a computer-graphic artificial world, usually with a head-mounted display.

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Components of a Telesurgical System

- *Manipulation Subsystem*
  - Hand-Controlled Master Manipulators
  - Servo Controllers
  - Slave Manipulators
  - Surgical Instruments
- *Imaging Subsystem*
  - Image Acquisition
  - Image Processing
  - Image Display
- *General and Ancillary*
  - Host Computer
  - Communication Link
  - Audio/Visual Communication

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Manipulators and Servo-Controllers

Desired Characteristics

- High Force Application
- High Stiffness
- Low Friction
- Low Inertia
- Gravity Compensation
- Six Degrees of Freedom
- Good Tracking
- Reasonable Cost
- High Precision
- Low Noise
- Sensitive Force-Feedback
- Fast Response
- Large Range of Motion
- Two-Handed Operation
- Coordinate Transformation
- High Reliability

Is it possible to satisfy all of the *technical* requirements for surgery? YES, but reducing telemanipulator cost and ensuring reliability will be challenging

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Input Controls and End-Effectors
for Telesurgery

Input	*Output*
– Keyboard – Joy stick – Track ball – Light pen – Data glove – Exoskeleton – Master manipulator – Electromyographic?	– Robot arm tracking operator's arm, joint by joint – Robot arm tracking input manipulator, not necessarily of congruent design – Gripper – Mechanical hand
– Instrument handle on master arm	– Instrument tip on slave arm

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Imaging Subsystem

- *Visible Light (Video)*
  - Monoscopic
  - Stereoscopic
  - Endoscopic
  - Microscopic
- *Other Imaging Modalities*
  - Magnetic Resonance (Real-time, Open Magnet)
  - Ultrasound
  - Infrared
  - Graphic and Pre-op Overlays

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Stereoscopic Displays

Method	Brightness	Resolution	Separation	Fatigue/Disorientation
Active Shuttered Glasses	fair	good	good	fair-good
Passive, Cross-Polarized Screen and Glasses	poor- fair	good	fair	good
Lenticular Screens	fair	good	good	narrow view angle
Head-Mounted LCDs	good	poor	excellent	poor-fair

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Stereoscopic Displays (cont'd)

- *All* stereoscopic displays produce eyestrain if the depth of field is large (vergence vs. focus). High resolution and good separation relieve this, increasing the useful depth of field.
- Monitor-based stereographic displays produce false, reverse parallax in response to head motion, unless the cameras track the observer's head position.
- Field-sequential stereo serrates fast-moving objects

Is there an alternative? Holography?

Will stereo video be good enough for most surgery? Probably.

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Stereo Endoscopy

Despite several reports showing endoscopic surgery to be faster with stereoscopic imaging, surgeons still seem to prefer monoscopic imaging. *Why?*

- Brightness? The monoscopic displays are brighter
- Resolution? The 3-chip monoscopic cameras are better
- Poor stereo? Most stereo endoscopes have little "intraocular" separation at the tip of the scope. The stereo effect disappears at distances greater than a few cm.
- Eyestrain? The light-shutter glasses seem to cause discomfort.
- Cost? Stereo is more expensive.

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Tactile Sensitivity

- Tactile information is derived from a combination of:
  - Touch receptor stimulation
  - Kinesthetic sense
  - Visual correlation
  - Exploratory intent
  - Multi-joint motion
  - Heat and pain sensation
  - Mental synthesis
- Will tactile information provided by a matrix of vibrating pins on a single finger tip be useful in surgery? (Compare three-finger manipulation to one-finger-tip scanning.)
- To what extent does loss of the tactile sense in surgery diminish the quality of patient care?

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Sensory Integration, Realism, and the Man/Machine Interface

- Haptic, proprioceptic, and visual fusion—*Achieving a sense of presence*
- Scaling of movement, force, and image—*How do differences affect performance?*
- Effect of image misplacement—*The "hand/eye axis"*
  - Image rotation ~ *very high*
  - Image scaling ~ *moderate*
  - Image displacement ~ *high*
  - Image stability ~ *?*
- Degrees of Freedom—*How important is six? Four is enough for some procedures, less for luminal surgery.*
- Fair and meaningful tests are needed that compare telesurgical systems with direct surgery and alternative surgical technologies.

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Ease of Use vs. Cost and Complexity

Ease of Use \ Cost and Complexity	Low	High
"Feels perfectly natural"	Ideal	Good Teleoperation
Awkward, adaptation required	Current laparoscopic technology	Poor Teleoperation

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Combining New Technologies to Augment a Complex Minimally Invasive Procedure

Procedure: Laparoscopic Colectomy

Technologies:
H.S. Harmonic Scalpel
H.M.D. Head-Mounted Display
R.A. Robot Arm (moves laparoscope)
3-D. Stereographic video laparoscope

	H.S. + H.M.D	H.S. + H.M.D. + R.A.	H.S. + H.M.D. + R.A. + 3-D.
No. of Cases	67	19	8
Time (min.)	173	157	143
Lens Cleanings/Hour	1 0.3	1.1	1.3

From: W. P. Geis, M.D., Minimally Invasive Training Institute, St. Joseph Medical Center, Baltimore, MD.

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Complex Laparoscopic Surgeries with Multiple Technologies

Procedure	Augmented by: – Head-Mounted Display – Harmonic Scalpel		Augmented by: – Robot Laparoscope Control – Stereo Laparoscope – Head-Mounted Display – Harmonic Scalpel	
	No. of Cases	Time (min)	No. of Cases	Time (min)
Colectomy	67	173	77	153
Gastric	16	184	7	155
Spine	19	228	8	125

From: W. P. Geis, M.D., Minimally Invasive Training Institute, St. Joseph Medical Center, Baltimore, MD.

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Factors in the Adoption of Robotic and Teleoperator Surgical Systems

- Medical
  - Efficacy
  - Enabling
  - Improved Patient Outcome
  - Safety
  - Time Saving
- Logistical
  - Cleaning/Sterilization
  - Ease of Set Up
  - Unimpeded Patient Access
- Financial & Operational
  - Capital Outlay
  - Per-Use Amortized Cost
  - Disposable/Consumable Costs
  - Offsetting Savings
  - Obsolescence
  - Surgeon Training
  - Nurse & Technician Training
  - Technical Support
  - Reimbursement
  - Need to Stay at the Forefront

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What Would Motivate the Adoption of Telepresence Endosurgery?

Cost Containment — Hospital costs would be reduced. Telepresence would enable more surgeries to be done "closed", reducing hospital stays, compared to open surgery. It would reduce OR time, compared to conventional endosurgical methods. Amortized capital costs would be small, if average utilization was two surgeries per day or more.

Patient Demand — Just as with "lap choly", patients will demand that other surgeries be performed closed when possible.

Surgeon Preference

— Laparoscopic surgery is time consuming and tiring compared to open surgery. Telepresence will make it easier.

— Many surgeons are reluctant to attempt the more difficult closed procedures; lacking the skill, the confidence, or the case load to keep in practice.

Breadth of Applicability — Potentially, the same telepresence surgeon console and system could be used for a broad range of endosurgeries.

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What would Inhibit the Adoption of Telepresence Endosurgery?

Capital Outlay — Hospitals may be hard-pressed to invest in new capital equipment, owing to smaller capital budgets and the need to replace existing aging equipment.

Other Technologies — Improvements to conventional endosurgical instruments and an assortment of less expensive auxiliary systems may chip away at the gap.

Improved Surgeon Training — Endosurgical simulators may get good enough to give surgeons enough opportunitiy to practice the difficult and less frequently performed procedures.

Natural Selection — Some surgeons seem not to be able to master laparoscopic technique. They may gravitate out of surgery, to be replaced by newer surgeons that have a natural ability to learn it. —The *Nintendo Surgeon* of the future.

Reimbursement —Delays in HMO acceptance of telepresence procedures could negatively impact this technology.

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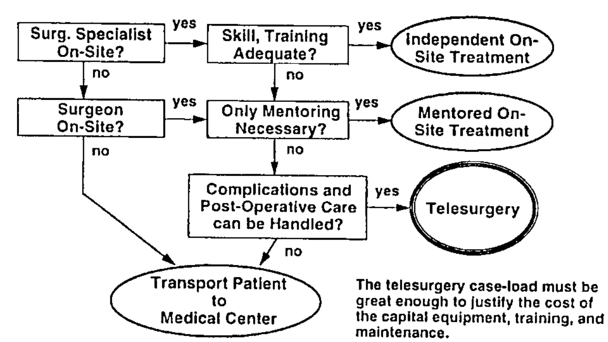
Decision Tree for Telesurgery at a Local Clinic



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Communication Link Issues in Telesurgery

- **Channel Reliability** (shared vs. dedicated)
- **Bandwidth** (dominated by video requirements)
- **Maximum Latency**

	time	1-way dist.
– For pyschophysical continuity	20 ms	3,000 km
– For stability with force-feedback	1 ms	150 km

- **Technology**
  - Point-to-point microwave
  - Fiber-optic
  - Low-earth-orbit satellite

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Research and Development Directions in Telesurgery

Basic and Exploratory Research

- Improved methodologies for studying teleoperation and optimizing operator performance under varied constraints
- Telesurgery under non-optical imaging (MR, ultrasound, CT, fluoroscopy)

Applied Research and Development

- Low-cost, highly reliable manipulator and servo technology
- Improved stereoscopic video
- Surgical cost-benefit analyses
- Fail-safe methodologies—servo and communication link

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Appendix F Safety Issues Presentation

Presentation given by: Brian Davies

There is a need to move towards an international consensus on how safe systems must be:

- To protect patients;
- To protect medical personnel (from litigation as well as physically);
- To re-assure system manufacturers/suppliers

Many of the points can only be completely resolved in detailed discussions of the specific procedure. However, hopefully it will be possible to get enough information to set out some general guidelines.

The area seems to break down into the following aspects:

- Traditional safety-critical systems issues (but considered from the special standpoint of RCAMI).
  - Should software be developed (as was suggested by UK Health and Safety Executive at one stage) by three different software groups in three different languages and run on different hardware so that motions are made only when all three agree?
  - Should systems be programmed in Ada, C++, any object oriented code?
  - Can a standard operating system be used (e.g., DOS) or must it be specially configured?
  - Is it OKto use standard computer hardware (e.g., a PC) or must it be ruggedized / modified?
  - Should formal methods always be used?
  - Should Failure-Mode-Effect Analysis always be used?
  - Should Fault-Tree Analysis always be used?
  - Should a separate emergency power supply always be supplied?
  - Should a "positive polling" electronic communication Bus be used to ensure integrity of sub systems and their communication? (e.g., of the type suggested by Imperial College in the European TIDE Project "M3S-Multiple Master Multiple Slave" in which a CAN Bus was supplemented by hardwired Key and "Dead-Man" Switch lines).
- pre-operative imaging, modeling and planning (applies to all systems; CAS or robotic)
  - What measures are provided to ensure correctness and accuracy throughout (e.g., that the imaging and 3D modeling are optimal for the task)?

- Are fiducial/anatomical markers identified throughout and available for subsequent registration?
- What pre-operative planning aspects are necessary to verify that the procedure is correct (e.g., that the displayed plan and the intended plan are the same, or that the simulation correlates with reality)?
- Are all assumptions built into the imaging/modeling clearly identified for the surgeon (e.g., regions where accuracy is diminished or tool motion is limited)?

- Issues associated with the use of a live (active) robot next to people, (Includes Tele-operators)
  - Lack of relevance of guidelines from industrial robotics (which discourage use next to people)
  - Should special purpose systems for the task generally be encouraged (e.g., of force levels, reach, and motions just adequate for the task), rather than slight modifications to industrial robots?
  - Should force sensors be added for each type of joint to trip if force exceeded (and/or could they just be motor current sensors)?
  - Should a mechanical constraining system be added to limit motions to a safe region if all software safety fails?
  - What safety software and sensor systems are desirable (e.g., should two position sensors be provided per joint, one at the motor and one at the joint output)?
  - For emergencies, should a "Dead-Man" switch approach be provided or should an emergency "off" switch be held by the surgeon? Alternatively, is it adequate to simply have an "off" switch in the vicinity?
  - Should the system always have a high reliability or is it enough that the system always fails to a safe condition?
- Issues of powered robots used passively (e.g., to carry a fixture or jig which, in turn, is used by the surgeon).
  - Should power be removed, and brakes be engaged, before surgeon is in vicinity?
  - Is it allowable for the surgeon to hold, say, a force sensor on the wrist and lead the robot to the final position?
  - Is it allowable for a large reduction gearbox to be added to the drives of the robot, to slow down the motion (recognizing that this increases the force levels proportionately) and if so, how close to the patient can it be positioned?
- Computer Assisted surgery
  - Should undesired motions of the surgeon (e.g., tremor, or motion into prohibited regions) be physically restricted?
  - Should only a warning be given?

  - Should localizers always give warnings when moving into areas of reduced accuracy, or is it adequate to stop the procedure (e.g., when a camera-based sensor is out of range or a manipulator arm is at its limit of stroke)?

- Tool registration at the start, and during, the procedure (i.e., of tool tip in camera based tracking, or of manipulator tip in arm based tracking, or of robot end point for robotic tracking).
  - What methods should be used to ensure optimal accuracy?
  - What warnings should be given to surgeons about conditions which lead to poor accuracy or reliability?
  - Is force control necessary for accurate registration?
  - Is it preferable to use fiducials screws, anatomical markers, or plaster casts containing fiducials?
  - How best to register points remote from the area of interest?
  - How best to register soft tissue?
- Intra-operative tracking of target.
  - In orthopaedics, should patient be rigidly clamped with a warning only if there is inadvertent motion, or should patient motion be allowed with dynamic referencing (i.e., the target location updated on-line)?
  - What features are required to verify that all is ok and incorrect advice is not being given? (unlike pre-operative planning, it is usually not possible to intra-operatively conduct tests of correctness)
  - In soft tissue, how should motion be tracked or compensated for?
  - Can/should change of soft tissue shape, when cut or pressed, be taken into account?
  - Should a dynamic referencing system have two separate means of measurement?
- HCI
  - How much information should be given to surgeons (pre and intra-operatively)?
  - In what form is it best displayed?
  - Should step-by-step instructions always be given, (e.g., sterilization sequence)?
  - Should surgeons have full awareness of limitations (e.g., of range of motions and forces)?
  - Should surgeons have full awareness of best practice in using systems (e.g., of regions of most/least accuracy)?
  - Should surgeons be aware of current status of all targets and tools and of percentage of plan completed, etc.?
  - Should all motions and instructions automatically be recorded?
  - In an emergency, what information is vital to display and what is confusing?

- Interruptions.
    - If procedure is interrupted, what verification is required to ensure all is still correct?
    - Should system be repositioned at start to re-register if interrupted?
    - Should system simply pause before continuing?
    - Should robots always re-play last motion sequence?

Appendix G Technology Transfer for Computer-Aided Surgery - Presentation

Presentation given by: Kirby G. Vosburgh

New Technologies follow three steps in their development:

- Creation
- Validation
- Utilization

Expanding this description for the technologies comprising high technology surgery:

G.1 Creation

The concept of aiding and enhancing the performance of physicians in interventional procedures has been created over the past decade. Diverse streams of research have been blended to create this new field including:

- New surgical approaches, such as endoscopy and semi-automated microscopy
- Advances in interventional radiology
- Advances in imaging
- Advances in computational support
- Applications of robotics technology to surgery

These elements impact all stages of treatment; in planning guidance, monitoring, and control.

G.2 Validation

This is the current stage of many of the concepts in the field. As will all technologies applied to medical care, the validation process has two principal elements:

- **Demonstration of Technical Performance** - This includes the effort to "show that it works" and demonstrating first order safety and creating a clinical test system.
- **Clinical Viability** - Here, the new technique is demonstrated to be clinically efficacious, safe, reasonable in cost, and generally superior to current practice. Many engineers underestimate the extent and difficulty of this stage, and fail to appreciate the care required to structure a sound, convincing clinical trial.

From an engineering perspective, the systems used in clinical validation will be more sophisticated than "production prototypes". They are designed to perform focused experiments to answer key questions pacing the structure of the clinical trials. Then, in the later stages, to be sufficiently robust to support tests with human subjects, while also being sufficiently flexible to permit optimization of the technique.

G.3 Utilization

When the technique is validated, commercial-quality systems may be designed. As computer-based systems and closed-loop automation become more widely used in medical care, (expanding from their current base in diagnosis and planning), a high standard or reliability must be maintained.

Thus, to the maximum extent possible, the new technique should be simple and robust -- pre-optimized for its task -- so that the physician cam concentrate on the case of the patient, not on the operation of the machine.

G.4 Some Positive Steps

As shown at this workshop, several factors are manifest to support early success:

- **Consistent Long Term Goals** - This work is characterized by the commitment and staying power of the medical and engineering leadership. They key issues are being understood in common, and being addressed with rigor.
- **Standardization** - There is progress on standardizing terminology, so that communication among workers (who represent different training, applied to a variety of professional disciplines, and working in a range of professional environments) may join forces effectively.
- **Technology Differentiation** - Some enabling technologies, such as thermal surgery devices or image segmentation algorithms, are unique to the field. Others, such as computers, are commercial units. Construction of a system then involves the integration of unique and commodity parts. Progress will accelerate to the extent that the commercial parts assume as much function as possible, with the simplest practical standardized interfaces. Benefits of increasing the commercial content of the system will include lower cost, simpler upgrading and improved safety, reliability, maintainability, etc.
- **End-User Pull** - The end-user of a technology (in this case, surgeons and other medical interventionists) are in the best position to set goals, and they are also in the best position to spot small "bumps in the road" that slow progress. The community of

leaders of the technology, as represented by the participants in this Workshop, is then able to smooth the bumps efficiently. In particular, clinical leaders will "pull" applications more smoothly than technologists will "push" them.

- **Bridging the "Valley of Death"** - In the development of many technologies, there is a gap in funding and institutional support as the research phases down, but before the rise of commercial development. As noted by Col. Satava, many good ideas die in this phase, where the practical challenges appear to be neither interesting to the research funding community nor profitable to the businessman. We can bridge this gap by maintaining interest, focusing our efforts on attractive demonstration projects, and stimulating early clinical participation.

Appendix H Image-Guided Tumor Diagnosis and Treatment

Presentation given by: Faina Shtern

Over the last few years, image-guided computerized interventions, such as laparoscopic, endoscopic, endovascular and radiologic, emerged as a minimally invasive alternative to major surgical procedures. The interest at the National Cancer Institute stems from the potential impact of computerized interventions, such as tumor biopsy and treatment, on the practice of oncology, radiology and surgery, when major surgical procedures may be replaced by minimally invasive, cost-effective ambulatory interventions.

In contrast to conventional surgery, imaging-guided interventions, which minimize tissue damage associated with surgical visualization and access, have the potential to reduce patient suffering, morbidity and mortality, recovery period, and hospitalization costs.

The clinical impact of computer-assisted procedures was shown in neurosurgery, where addition of CT imaging reduced morbidity of stereotactic brain biopsy from 30% to less that 1%. More recently, image-guided percutaneous stereotactic breast needle biopsy has been demonstrated as a minimally invasive, cost effective alternative to diagnostic open surgical excision for patients with non-palpable lesions. In contrast to open surgical biopsy, stereotactic breast biopsy is a simple, automated procedure, which causes no pain or disfigurement. The cost of stereotactic procedures is about 28% of that for surgical biopsy. Even conservatively estimated, presuming that only 35 to 50% of surgical biopsies will be replaced by stereotactic procedures, the annual national cost savings are predicted at about 0.4 to 0.8 billion dollars.

Minimally-invasive procedures, however diverse, have two common features: 1) digital images; and 2) remote manipulations. In a subjective, arbitrary manner, digital images may be divided in two major groups. Video camera-based images may be generated during endoscopic, laparoscopic and some endovascular interventions, when field of view is limited in size and visualization is limited to tissue surfaces. Radiologic modalities, on the other hand, are unique in their ability to provide subsurface three-dimensional visualization, with large field of view.

As opposed to digital image-based synthetic reality, virtual reality is a computer simulation of surgical experience. Virtual reality may take image-based synthetic reality one step further, when visualization may be combined with simulation of other surgical experiences, including manual, vestibular, kinesthetic [and even olfactory] influences.

Digital image display, in turn, creates a possibility of a remote manipulation, which is essentially an interaction of a surgeon with internal tissues via computerized reality, rather than direct surgical access and visualization. In essence, the computer workstation becomes a patient substitute.

One can imagine that interactive surgical computer workstations, including virtual reality systems, may be interfaced with telerobotics, such as for instance robotic arm, which may follow human movement during intervention with great precision. Such an interface would then allow for surgery either a few feet away, or a few hundred miles away. Of course, real time telesurgery raises a number of important questions of high performance, low cost telecommunications of the future.

While we are on the subject of the "futuristic" possibilities, image-guided robotics-driven surgery comes to mind. The potential role of robotics in image-guided interventions is quite intriguing for several reasons, including their potential to improve human dexterity. Recently, an image-guided robot has been used for retinal surgery and orthopaedic procedures, and other robotic applications are under development.

Future trends in image-guided computerized interventions may include: 1) Real time 3D visualization; 2) Virtual Reality; 3) Telesurgery; 4) Robotics; and 5) Telecommunications. Based on the future promise and exciting vision for this field, NCI is currently considering a joint program with NASA, Ballistic Missiles Defense Organization and the Society of Cardiovascular and Interventional Radiology entitled "Technology Transfer in Image-Guided Tumor Diagnosis and Treatment".

The goal of this effort is to advance the current state-of-the-art in image-guided tumor diagnosis and treatment through transfer of defense, intelligence and space technologies. In order to achieve this goal, we intend 1) to review current fundamental technologic roadblocks; 2) to develop a technologic problem statement; 3) to conduct a national search; and 4) to evaluate the applicability and clinical relevance of the identified defense, intelligence and space technologies. We created eight technologic teams, covering such areas as 3-D Imaging, intra-operative guidance, real time imaging, surgical workstation design, telesurgery, virtual reality, telerobotics, and telecommunications. The next step will be to complete a technologic problem statement for four specific oncology areas: Head & Neck Tumors; Breast Cancer; Prostate Cancer; and Liver Metastases. This problem statement will be circulated to over 250 defense, intelligence and space laboratories.

In summary, the art of radiologic imaging, when combined with computer science, robotics and advanced information technologies may redefine the practice of medicine, oncology and surgery. Surgical interventions may become more safe and effective in order to reduce pain and suffering, to improve quality of life. We hope that the national program currently under discussion between NCI, other government agencies and the academic community will make a modest contribution to the achievement of this future vision.

Appendix I Working Group Framework and Goals

(Distributed Before the Workshop)

The Robotics and Computer Assisted Medical Interventions (RCAMI) workshop will be divided into four working groups, each with its own area of focus. The goal of each working group will be to examine issues, needs and requirements related to a particular RCAMI *application area*, and to identify areas, tasks, and problems for future research and development. This pre-workshop report offers an initial framework for discussion by defining the four application areas, and a variety of technical and non-technical issues which span each of the application areas. In addition, within each application area a number of example systems and issues are presented in an attempt to differentiate the four application areas.

The four RCAMI working groups will be charged with investigating issues related to the following application areas:

1. **Surgical Simulation** - including physical-based modeling, biomechanical simulation, visual and haptic interaction; for use in applications such as teaching, training, pre-treatment planning and rehearsal.
2. **Image Guided Procedures** - the intra-operative use of computers, sensors, graphics, etc. to assist or guide a surgical procedure, usually based upon pre-operative medical images. Does *not* include active or semi-active robotic systems.
3. **Robotics/Manipulators** - the intra-operative use of active or semi-active robotic/manipulation systems to assist in image-guided surgical procedures.
4. **Teleinterventions** - the use of remote information and/or guidance in medical interventions involving the transduction and transmission of perceptions and/or actions at a distance.

In addition to the four application areas, five *enabling technologies* have been identified which span the four application areas. The enabling technologies provide the building blocks which are necessary for development within the application areas. Each working group should examine issues related to the intersection of the enabling technologies with the group's application area. Enabling technologies have been classified into the following categories:

1. **Augmented or hybrid reality displays** - devices which permit the combination of real and virtual worlds to produce an enhanced sense of reality.
2. **Medical imaging technologies** (e.g., X-Ray, CT, MRI, PET, Ultrasound, etc.) - anatomical and functional imaging of the human body for use both pre- and intra-operatively. Includes novel interventional imaging technologies.
3. **Non-medical sensing and imaging technologies** - (e.g, position estimation sensors, range

imagers, video cameras, etc.) - for accurate and reliable measurement of patient anatomy, surgical tools, surgeon's head position, etc.

4. **Registration methods** - for identifying the spatial relationship between two or more representations of the same structure (e.g., a pre-operative CT image of a skull to multiple intra-operative X-Rays of the same skull). The resulting spatial relationship may be rigid or deformable.
5. **Medical image processing and understanding -** the low level manipulation and/or high level interpretation of medical images to extract relevant structures and information.

There are three technical issues which can not be classified as enabling technologies, and yet have implications to each of the four application areas. The intersection of these *common technical issues* with each application area should also be explored by the working groups.

1. **System validation and requirement specification** - the validation of RCAMI systems in terms of accuracy, usability, robustness, etc. The task-specific determination of system requirements in terms of accuracy, reliability etc. This is an area which has not received sufficient consideration in the past, and will require increasing attention as more RCAMI systems become used in the clinic.
2. **Minimally invasive procedure design -** the trend in surgery from procedures with large explorations and exposures to procedures with limited access and restricted direct visibility.
3. **Design for safety -** design of RCAMI systems to ensure safe and reliable operation.

Finally, several *non-technical issues* which are common to the RCAMI application areas should be examined. These issues include:

1. **Clinical evaluation and cost benefit analysis** - How to determine if new technology improves patient outcomes? What is the meaning of improved outcome? Lower costs? Reduced complications? Is the technology economically feasible for clinical use?
2. **Acceptance** - Will the technology be readily accepted by physicians, hospital boards, patients, insurance companies, regulatory bodies?
3. **Regulatory issues** - Should this technology require sanctioning from government bodies in terms of licensing and training? To what extent?
4. **Liability** - Who is liable if the technology fails?

A summary of the application areas and the common issues / technologies is presented in Table I-1. The directive of each working group is to explore the intersection between the applications areas and the issues / technologies as represented by the shaded region of the table. Several comments regarding the framework in this table are warranted. First, the terminology, definitions, and issues implicit in the framework are meant as a *starting point* for discussion by the working groups. Groups should feel free to expand upon or modify this structure as they choose. Second, there is inevitable overlap among the various application areas. Each group should be aware of the domains of the other groups in order to avoid duplication of effort. For example, while pre-operative planning is an essential component of

Image-Guided Procedures, the Surgical Simulators group will have primary responsibility for issues related to pre-operative planning.

An additional goal of the workshop will be to generate definitions of commonly used terminology within the RCAMI field. An initial list of terms requiring formal definition is presented below; however, working groups should feel free to suggest additional terms. Each of the working groups has been assigned a set of terminology to define as specified in Table 2. The terms under the heading "Common Issues" should be defined by each of the working groups.

What follows is a more detailed description of each of the four application areas. Key technologies, example systems, and basic issues are presented in an attempt to better define the application areas.

I.1 Surgical Simulators

In the context of the RCAMI workshop, the application area's of surgical simulators include: physical-based modeling, biomechanical simulation, visual and haptic interaction; for use in applications such as teaching, training, pre-treatment planning and rehearsal.

Some of the key tools in this area include mathematical modeling techniques such as finite element analysis, kinematic analysis, deformable modeling methods, and surgical procedure optimization. Other relevant tools include visualization techniques, computer graphics, haptic modeling and transduction, and anatomical model creation.

Surgical simulators can be used in a number of different applications including [3]:

1. Medical education - for instructing students in areas such as anatomy, physiology, and biomechanics (e.g., interactive multimedia presentations of anatomical atlases).
2. Training and accreditation - developing and evaluating skills required by clinicians for performing particular tasks (e.g., laparoscopic tools usage, spinal tap insertion). These technologies also provide a mechanism for quantitatively evaluating surgical skills based upon a common evaluation metric.
3. Surgical planning - for pre-operative decision making regarding how a given procedure will be performed. May incorporate tools for predicting and optimizing surgical outcomes. Also provides the ability to rehearse a procedure and refine techniques.

Physical-based medical simulators have been compared by some to flight simulators which are commonly used for safely training pilots [20]. Simulators provide a risk-free environment for exposing the trainee to a wide variety of scenarios. These scenarios may include infrequently occurring complications which a typical student might never otherwise experience during training. Both medical and flight simulators have very high realism requirements. The

		Application Areas / Working Groups			
		Surgical Simulators	Image-Guided Procedures	Robotics / Manipulators	Teleintervention
Enabling Technologies	Augmented / Hybrid Displays				
	Medical Imaging Technologies				
	Sensing / Imaging Technologies				
	Registration Methods				
	Medical Image Processing and Understanding				
Technical Issues	System Validation and Requirement Specification				
	Minimally Invasive Procedure Design				
Non-technical Issues	Safety				
	Clinical Evaluation & Cost Benefit Analysis				
	Acceptance				
	Regulatory Issues				
	Liability				
	Other?				

Table I-1: Common issues / technologies: interaction with application areas

Surgical Simulators

- Virtual reality
- Surgical simulator
- Physical modeling
- Pre-treatment planning

Image-Guided Procedures

- Computer-assisted surgery
- Computer-controlled surgery
- Image-guided surgery
- Robot-assisted surgery

Robotics / Manipulators

- Medical robot
- Powered and unpowered robotic arm
- Passive, semi-active and active robotic arm
- Passive and/or Active compliance
- Interventional robotic arm

Teleintervention

- Telepresence
- Telemedicine
- Telesurgery
- Teleintervention
- Telemanipulator

Common Issues

- Registration
- Calibration
- Augmented reality
- Hybrid reality
- Minimally invasive procedure

Table 2: Terminology to define within application areas

training environment must be sufficiently similar to the actual environment in order for the simulator to be beneficial.

One colleague has suggested that medical simulators should possess the following criteria in order to be convincing [21]:

1. Fidelity (high resolution graphics).
2. Organ properties (deformation from morphing or kinematics of joints).
3. Organ reaction (such as bleeding from artery or bile from the gall bladder).
4. Interactivity (between objects such as surgical instruments and organs).
5. Sensory feedback (tactile and force feedback).

General issues related to the area of medical simulators include: the need for accurate anatomical modeling; the need to incorporate patient specific information; and the requirement that simulations must eventually be validated against reality to ensure effectiveness.

Some examples of surgical simulation systems which have been submitted in the pre-workshop papers include: Georgia Institute of Technology's eye surgery training simulator [22]; Delp's biomechanical muscle simulator [7]; Delp and Rosen's Military Medical Trainer [6]; and Kaneko's ear reconstruction system [16].

I.2 Image Guided Procedures

In the context of the RCAMI workshop, Image Guided Procedures include the intra-operative use of computers, sensors, graphics, etc. to assist or guide a surgical procedure, usually based upon pre-operative medical images. Active or semi-active robotic systems are explicitly omitted from this application area as they are addressed in the Robotics/Manipulators area.

Image-guided systems typically use either pre- or intra-operatively acquired medical images for assisting the surgeon in a guidance or navigational task. During surgery, the position of surgical tools and patient anatomy may be tracked so that correspondence can be established between the imagery and the current surgical state. By relating this state information to a pre-operative plan, feedback can be derived and presented to help guide the surgeon towards achieving a particular goal.

In a recent paper describing an image-guided stereotactic biopsy system, several desirable properties for image guided systems were presented [4]:

1. The need for accuracy and stability over time.
2. No impediments to the movement of the surgeon or the patient.
3. If a position localizer is used, its integration into the surgical environment should be seamless.
4. A number of different surgical instruments should be easily integrated with the system.

5. Multiple imaging modalities should be possible.
6. The surgeon's direct interactions with the software should be minimized.
7. The interface to the system should be as intuitive as possible.
8. A means for comparing the results obtained via image-guided and conventional approaches should be possible until confidence is developed.
9. Redundancy should be built-in; failure of the image-guided component should not require terminating the procedure.
10. Modularity should be built into the system so as new technologies become available they can be easily integrated.

Most of the enabling technologies such as medical imaging, sensing, tracking and registration play important roles in the context of image-guided procedures. It is expected that future developments in these technologies will greatly enhance the capabilities of image-guided systems. Current limitations in image-guided systems can be attributed primarily to deficiencies in these underlying technologies.

Validation and critical evaluation of any image-guided system must be performed before it can be used on a widespread clinical basis. Validation should include studies regarding possible failure modes, component and system accuracies, interface and usability issues, etc. In addition, clinical evaluation must be performed to demonstrate that the image-guided outcome warrants the expense and development of the device.

Some examples of image-guided procedures which have been submitted in the pre-workshop papers include: the ISG Viewing Wand [14]; the Grenoble group's ACL reconstruction and grafting system [8]; StealthStation for pedicle screw insertion and other procedures [11]; and Edward's surgical microscope augmented reality system [9].

I.3 Robotics / Manipulators

In the context of the RCAMI workshop, Robotics / Manipulators will include the intra-operative use of active or semi-active robotic/manipulation systems to assist in image-guided surgical procedures. The terms active and semi-active are defined as in [5]:

> A *semi-active* system is one in which: "the action is physically constrained to follow a pre-defined strategy. The action is guided which means that the intervention is performed with respect to a previously defined strategy, but its final control depends on the surgeon".
>
> An *active* system is one in which: "some subtasks of the strategy are performed with the help of an autonomous robotic system, supervised by the surgeon and controlled by redundant sensors".

While a lot of research has been performed in the area of rehabilitation and medical service robots [10], in the context of the RCAMI workshop, the robotics/manipulators application area will be limited to robotic systems that are used during the course of a medical procedure.

Recognized advantages of robotic systems include: the ability to accurately position and reposition surgical tools; the ability to apply precisely calibrated forces; the potential for a reduction in tremor as compared to human hands; the ability to scale the magnitude of forces and motions either larger or smaller than those possible by humans; the ability to provide a rigid platform for supporting cameras or surgical tools in a tireless manner.

Recognized limitations of robotic systems include: current commercially available robots are intrinsically unsafe and not meant for direct interaction with humans; when active robotic systems are used, the surgeon must relinquish a certain amount of control to the robot - therefore the ability to monitor the system's progress is paramount; autonomous robots are only as reliable as the strategy and software which controls them - unexpected conditions can be problematic; mechanical robotic systems may require frequent calibration to ensure accurate operation.

Some of the issues in this application area include:

1. Should robots be designed on a procedure-specific basis, or is it possible to build general purpose medical robots which satisfy the requirements of a large number of procedures?
2. For what types of procedures should a robot be used? What task requirements best match the strengths of robotic systems? Does a procedure require a robotic system or can some other approach be used?
3. How can the safety of the system be ensured? Are there alternative approaches in the event of failure midway through a robotic procedure?
4. How much system redundancy is required and how should it be incorporated into a design?
5. How should robotic systems be designed so that they are easily controlled and monitored by the surgeon?

The Robotics / Manipulators application area has some overlap with other areas. For example, telesurgical systems may require robotic hardware very similar to that required by active robot systems. However, requirements for such systems may differ in terms of control, sensing and transduction abilities, status monitoring, etc. Robotic / manipulation systems also rely heavily on surgical simulation for construction of pre-operative plans.

Some example robotic systems include: RoboDoc - a system for femoral milling in total hip replacement surgery [17]; Taylor's laparoscopic camera positioning robot [23]; Masamune's MRI needle biopsy system [18]; Aesop laparoscopic camera positioning robot [20]; Brett's ear drilling system [2]; and Harris' prostate resectioning robot [12].

I.4 Teleintervention

In the context of the RCAMI workshop, teleintervention is defined as the use of remote information and/or guidance in medical interventions involving the transduction and transmission of perceptions and/or actions at a distance.

In the broadest sense, teleintervention encompasses everything from remote surgery with robotic end effectors to interactive surgical consultations, teleconsulting, and remote diagnosis. For the RCAMI workshop, the term teleintervention applies to the remote use of robotic systems (i.e., telerobotics), interactive surgical consultation, and remote patient examination / diagnosis. It does not include non-real-time teleconsulting such as performed by some radiological reading services. Teleinterventional applications that attempt to reduce the "distance" between the specialist and the patient while making these interactions as seamless as possible are the primary focus of the teleinterventions working group.

The teleintervention application area has a large overlap with the robotics/manipulator area. As mentioned above, robotics technologies are often required for use in telesurgical systems. Also, teleinterventions can draw upon techniques developed for image-guided procedures for tasks such as guiding a remote medic through a surgical procedure.

Some of the key issues to be addressed in the teleintervention application area include:

1. Communication and device bandwidth requirements. How much bandwidth is needed to perform a particular task?
2. Latency - How much latency can a teleintervention system tolerate before becoming unusable? How can latency problems be reduced?
3. How can patient confidentiality be ensured?.
4. How can teleinterventional user interfaces be designed so that clinicians feel as if they are present at the remote site?
5. What technologies are required to allow the sensing and transduction of tactile and haptic sensations.

Some examples of teleinterventional systems include: SRI's remote manipulator system [15] [1]; Moore's telementoring laparoscopic system [19]; and Howe's remote palpation work [13].

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Appendix J Workshop Questionnaire Response Summary

This section of the report has been compiled by grouping the responses from the workshop participant questionnaires. The contents of the responses presented below have not been modified in any way. Among the questionnaire respondents, the average number of years working in the RCAMI field is: 8.2. The breakdown of primary area of interest among respondents is:

• Image-guided procedures	22
• Robotics / Manipulators	10
• Surgical Simulators	15
• Teleinterventions	6

J.1 RCAMI Common Issues and Technical Problems

What are the major technical problems and research needs in RCAMI?

Imaging technology (displays); hardware (manipulators, actuators); communications (real-time codecs); networking; FDA and equivalents; well-defined applications; understanding of cognitive/psychomotor skills and skill acquisition in surgery; lack of quantitative metrics; aggressive testimonial presentations; legal problems; safety measures; time delay; surgeon-machine interface; precision of telemanipulators; image quality; lack of funding; limited physician understanding of technical possibilities; lack of engineering understanding of physician patient needs; need for decreasing cost of technology; need for robotic devices capable of tissue handling; post graduate education; need for real time high resolution video on image transfer; technical problems associated with the challenge of cost reduction; sterilizability; cleanability; reliability; maintainability; compatibility with existing surgical equipment; awareness of alternative technical (& pharmaceutical) approaches that would abbreviate RCAMI; assessment of value added with each increase in complexity; selection of economically viable clinical applications; inadequate realism and breadth and richness of the experience in surgical simulation in order to develop more effective interfaces for telemanipulation; improvement needed to stereographic visualization; resolution and dynamic range improvement needed in head-mounted displays; mechanical design of small multi-dof manipulators with high stiffness, low friction & backlash (good reliability); understanding of what surgeon do in various procedures (which actions are essential, which are not; what sources of information are used, which ignored, etc. coordination of visual and kinesthetic motion; registration of 3-D imaging with mobile tissues; ignorance -- engineers of medicine - physicians of technology; suturing; palpation; cooperative manipulation -- robotic assistance to surgeons; minimizing trauma to tissue during grasping & manipulation; lack of measurement of mechanical properties of tissues; fundamental relationship between task description and dexterity require-

ments; variety of opinions among surgeons (often contradictory!); fully automated segmentation; real time see through displays; methods for visually tracking position of scopes relative to 3D scans; realistic simulations (i.e., haptics & visual); effective in-theatre registration and tracking; effective 3D monitoring of patient in real time; fusion of real time and pre-operative sensor information; clearer definition of clinical requirements; sufficient dexterity for surgical task; solution to problem of need for real-time response; standards lacking; metal artifact (CT&MR); real time 3D imaging; generalizability of results; stereolithography is too expensive; motion blurring; target definition requires multimodality; MRT experience is limited; CT fluoroscopy; lack of concepts; tool development; acceptance by MDs; integration imaging technology (accuracy, speed, size, cost, existence of invisible tissue); image processing method (analysis - [segmentation, etc.] recognition [understanding], display [graphics, etc.]); sensing device like fingers and hands of human; man-machine interface (mechanical I/O, audio and visual) models and physics of human tissue (skin, muscle, bone...) computers and processors (size, weight, robustness, operability, fail-safe system) mechanics (way to manipulate living organs by machine); basic data/model collection and establishment; normal database establishment; conduct control studies; cost effectiveness; availability of information in a timely basis; reliability; depth perception; clinical lag; new skill requirements; lack of outcome evidence; stereotactic errors; lesions localization; medico-legal anxieties; training of staff; clinical requirements; apathy; space of the operative field; duration of RCAMI-specific tasks; lack of infrastructure; need for skilled personnel; quality of conventional procedures; lack of clinical collaborators that are willing to truly immerse themselves in these problems; lack of technical people willing to truly understand clinical needs; standardized test data sets for comparing algorithms/reporting results; making successful software generally available for use by the community (must permit integration of future developments); patient acceptance levels; device reliability; inadequate clinician training; inadequate peripheral monitoring; insufficient design guidelines; sensors for touch; distributive sensing and actuation techniques; confidence in the business community; risk assessment methods; operating set up times; guarding intellectual property; difficulty with institutional review boards; strapped financial situation of US medical schools; desire in others to “reinvent the wheel”; demands on educating others once a system has been approved for general use; lack of standards between imaging technologies for file transfer; physician confidence; perception it is “costly” affordable systems; end effector “tool” development; anatomical based simulations; patient motion-image update; real-time intra-operative imaging and image reconstruction; legal ramifications of telesurgery; compactness of mechanisms, segmentation; commonality of software; non-technical users; pre & intra-operative planning; augmented benefit from computer assisted planning (by FEM-analysis, atlases); No pressure on NHS hospital to pursue these sort of activities; Lack of support from manufactures - particularly in the UK; too early commercialization in MRCAS; dexterous manipulator; security of network; accuracy of data globe; sectionalism among hospital departments (esp. radiology), who pays the cost?; medical

insurance system; lack of funding (conflict between NSF (no medical) and NIH (no technical)).

Table J-1, which spans several pages, further develops nine of the most commonly addressed technical issues and problems.

What areas in RCAMI are currently NOT receiving enough attention?

Fundamental human performance/human computer interface issues; micro technology (MEMS); legal problems; pathology affecting soft tissues (i.e., chest, abdomen); sensory feedback (force, touch, vision); methods for careful validation of segmentation & registration; safety; integration of real time sensor information with pre-op information (sensor fusion and augmented reality); lack of training; planning and guidance systems; evaluation - by rigorous methodology (RCT); generalizability of results; low cost systems; image guidance; therapy methods; clinical trials; basic model and data development; reliability study; robustness of computer networks; endoscopy; system engineering for applications marketing; algorithms and implementations; latency; development of a completely reliable imaging file organization; integration of head mounted displays into image guided surgery; integration of micro robots into image guided surgery; development of surgical robots for use in amenable surgery, e.g., orthopaedics; development of registration devices to guide surgery; inexpensive image guidance systems for image guided therapy; infrastructure & standards; alternative solution (non-RCAMI) for clinical problems in the UK; manipulatory robotic; formation and coordination of international databases; development and distribution of normative data; methods for careful validation of segmentation & registration; realistic haptic/visual integrated simulators.

What piece of technology do you wish that you had today?

A robotic device for tissue manipulation; tactile shape display with high force, high resolution, high bandwidth; combination of functional mapping and CAS; cheap intra-operative 3D image and sensing system; cone beam CT & 3D fluoroscopy; automatic volume image segmentation and labeling; real-time image processing; 3D rendering; very accurate imaging technology such as recording details of soft bone, soft tissue, and of 3D images of moving heart; real-time distance imaging with tactile feedback; a "good" robot; integration of CT, MRI, PET, Ultrasound, Atlas information; a reliable free-hand endoscopy system for endonasal surgery; a digital operating microscope with integrated CAS-system; real time MR image acquisition/3D volumetric reconstruction of anatomical objects; 100 Gbs/networks lower latency; surface actuator methods; lightweight stereoscopic head mounted display; computer based registration devices in the operating room; real-time data feedback; anatomical based simulator; automatic registration of real time images to pre-op scans; compact, lightweight, accurate 3D imaging device; non-intrusive, passive, non-line-of-sight 6 Dof positioning device accurate to ~0.1 mm/~0.03^{o}; optical localization system (optotrak) too

	Technical problem or research need		
	Surgical compatible RCAMI devices	Sharing autonomy in the operating room	Other institutions reinventing the wheel
Why is this an important technical problem?	Most actual devices are assembled and adapted components developed for industrial applications. The human operator closing the loop and interacting with these technical devices, the environmental and other (illegible) has to been taken into account.	Robotic devices have capabilities that human surgeons lack. But surgeons have judgement (and responsibility) that robots lack. The fundamental challenge is how can a human exploit the ability of the machine in cases that are neither purely preplanned (e.g. stereotaxy) or simply master-slave manipulation.	Many investigators in the field see a piece of research and immediately repeat it, attempting to claim if for their own. This leads to a great deal of wasted time and effort. As the same device is invented at multiple institutions (for example, our device, the optically tracking surgical navigator) has been recreated by at least six different other entities.
What are the difficulties?	Special constraints (concerning sterility, workspace, safety, etc.), intra-operative handling and interaction, non-technical users: interaction within the worksystem.	Dynamic model updating, sensor "fusion", human factors/human-machine interfaces, context-sensitive command interpretation, safety/verification.	Rather than working together and solving individual aspects of the problem, multiple institutions and companies are trying to reinvent the entire device.
On a scale from 1 - 5 (5 very difficult) how difficult is it to overcome?	3	3	5
What is the probability it could be solved in 2 years?	50%	90%	5%
How many years will it take to solve and at what cost?	4 years at $1 Million per year	3 -5 years at $1Million per year	N/A

Table J-1: Technical problems and research needs in RCAMI (continued on next page)

	Technical problem or research need		
	Real-time 3D imaging	Robust registration of 2D to 3D images	creating/evaluating/validating usefulness
Why is this an important technical problem?	Navigation and monitoring in 3D is essential for safety and accuracy	3D modalities (CT, MRI, etc.) provide excellent information for treatment planning but are not practical for many surgical procedures. "Light-weight" imaging sensors such as video or x-ray fluoroscopy are 2D in nature.	At the base of many proposed application. It's difficult to know what's better without more direct comparison/evaluation. Rigorous testing on standardized data sets is often lacking in our field.
What are the difficulties?	Current systems are largely 2D or 2 1/3D, complex data acquisition & display problems have not been addressed.	Robustness-methods must work well and accurately without requiring massive fixturing (e.g., portable c-arm rather than biplanar machine). Efficiency-methods must work quickly on relatively low-cost equipment.	Requires organization, funding and someone willing to dedicate time to this. (some progress has already been made, though in the U.S., the NIH has funded comparison of registration algorithms). Getting researchers to agree on what a standard dataset is might be touch.
On a scale from 1 - 5 (5 very difficult) how difficult is it to overcome?	5	5	4
What is the probability it could be solved in 2 years?	10%	80%	50%
How many years will it take to solve and at what cost?	5 years at over $10 million per year	3 - 5 years at $1-10 Million per year	2 - 3 at $10 Million per year

Table J-1 continued - Technical problems and research needs in RCAMI (continued on next page

	Technical problem or research need		
	Palpation information (Tactile feedback)	Making soft tissue models	Telepresence/ Telesurgery
Why is this an important technical problem?	Only way to distinguish mechanical properties of tissues. Often used in conventional surgery to locate hidden structure (tumors, arteries, lumens, etc.)	Almost all surgical simulators will involve soft tissues, a realistic simulator will require realistic modeling of soft tissues, realistic outcome prediction will require realistic modeling of soft tissues.	Critical for emergencies (ex, military operation, natural disasters) other medical emergencies when surgical and/or subspecialty expertise is needed.
What are the difficulties?	Don't know what surgeons sense w/fingers and why. For feedback, difficult to build tactile display devices. For autonomous robotic system, difficult to automatically interpret tactile sensor signals. Need to relate sensory info (vision, touch) to controls.	How to represent the model? Soft tissue is not homogeneous and has complex internal structure that can grossly affect material properties (i.e., how it stretches, tears, deforms, etc.). Conventional graphics models (surface polygons, solid geometries) can not easily incorporate this complexity, other representations (e.g., volumetric or voxel-based) require basic research in object represented and modelling physically-realistic object interactions as well as ways to deal with image data sets.	High performance, low cost, robust computer networks, safe and effective (proven) technologies
On a scale from 1 - 5 (5 very difficult) how difficult is it to overcome?	2 - hard tumor in soft tissue 5 - autonomous robot for bowel retraction	4	5
What is the probability it could be solved in 2 years?	100% for hard tumor 10% for autonomous robot	30%	0%
How many years will it take to solve and at what cost?	5 years at $1 Million / year	5 years at $1 Million / year	5+ years at $10 Million / year

Table J-1 continued - Technical problems and research needs in RCAMI

expensive; surgical simulator telesurgery system; self contained 6 dof micro-localizer, mountable on a tool tip; non-contact non-wired low-size component line of sight independent navigator.

What are some of the key hurdles to overcome in sensing?

3-D Reconstruction/display of sensory data; tactile sensing in a realistic way is still far away; endoscopes with improved dexterity and intuitive control interface; tracking mobile tissues (organs, joint, etc.); wireless and accurate; price; integration of video with other technologies esp. ultrasound; low dose x-ray; development of versatile 3D ultrasound; sensing the tip of flexible tools (catheter, endoscope); improved intra-op imaging; non-invasive measurements; radiation; size of sensors/devices/modelling; detectors; displays and perception; making systems less sensitive to working environment.

What are some of the key hurdles to overcome in execution?

Micro instrumentation; simpler designs; lower cost motors; inherent reliability (hardware & software) in the hands of ordinary medical support staff who have little time - all these would help; ergonomics of interfaces; coordination of kinesthetic control & visual feedback; 3D real time visualization system with contrast mechanism to update as procedure/intervention proceeds; non-invasive measurements; efficient ways to code complex tasks for distributed processing; sterilization of key devices and sensors to invasive use; registration and image rendering speed

What are some of the key hurdles to overcome in planning?

3-D data sets; rapid conversion of imaging data to the form needed for planning; use of the diagnostic imaging modality required for standard work up, without having to do extra scans just to satisfy needs of the computer-assisted planner; deformation; integrating fast but cost-effective computing systems with 3D voxel models derived from multiple sources for effective planning tools; automatic segmentation and labeling; real time image processing; quality of original images; I/O devices in the simulation; sub micron models; patient acceptance; better models; lesion segmentation; registration; display mapping; human interfaces.

What will be possible over the next 25 years?

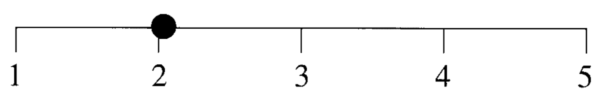
Numerous endoluminal (endovascular, GI, neurosurgery); focusing destroying energies for non-invasive tumor treatment; simulation of surgical approaches for non-fixed organs, robotic assistance for surgery of these organs; incisionless surgery using transcutaneous technology such as high intensity focused ultrasound; 3D sensor should be more easy-handled; brain shift

during the surgery should be overcome; extending minimally invasive image guided procedures to other parts of the body esp. abdomen and pelvis; 3D Rad Tx; minimally invasive Tx: CABG; bowel anastomosis; node dissection; image guided endoscopy MR guided FUS; recording images augmented by much more details of organs and tissues in human body; distance procedures; microsurgery; surgery within confined spaces; cochlear surgery for tinnitus; retinal implant; model-based functional septum surgery; less invasive heart bypass surgery; a host of laparoscopic procedures; telerobotic brain transplantation; extreme minimally invasive surgery using micro-robotics into critical areas of the brain; further shrink the surgical field into the microscopic range; complex orthopaedic alignment procedures; soft tissue repositioning procedures; tumor excision procedures; customized preparation/insertion of body parts/ substitutes; various forms of conformal localized therapy; contact less percutaneous localization.

J.2 Image Guided Procedures

On a scale from 1 - 5 (5 being very difficult) how difficult has it been to convince medical colleagues, research colleagues and patients (if applicable) to support image guided procedures?

Medical Colleagues:

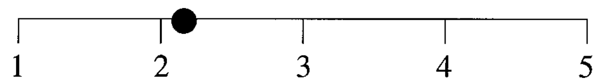


Medical Colleagues: 2.02

What are the main areas of resistance from medical colleagues?

Accuracy; reliability; safety; clinical relevance; cost effectiveness; benefits are obvious; understanding concept; suspicion of "high tech" procedures and their cost; as computers have become used more widely in medicine - physicians are more willing to accept practicability; PACS/IMAG systems; what real improvements are provided (e.g., conformal 3d treatment planning); too complicated takes too much time; use of expensive imaging technologies (e.g. CT Scans) as basis for computer assisted surgery procedures; cost of hardware; most realize computers can provide considerable assistance; need to show concrete definite advantage; time stress in clinical routine; need to registration of systems with patient to sub-millimeter level; It's a new concept that requires repeated review so that clinical colleagues begin to see application in their field; learning time; non user-friendly systems; Ego problems; missing educational background.

Research Colleagues:

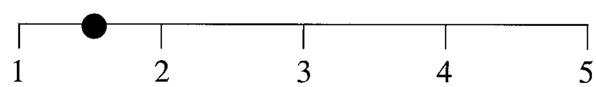


Research Colleagues: 2.10

What are the main areas of resistance from research colleagues?

Technical feasibility; cost effectiveness; theoretical/research problems are few -- haven't the interesting issues been addressed; lack of convincing scientific database; preference for robotic systems; defining a real scientific problems; the only obstacle was the desire to protect one's intellectual property; funding; Reliability & Cost; absence of standards or accepted leader; no main obstacles.

Patients:



Patients: 1.50

What are the main areas of resistance from patients?

How accurate is it? safety/morbidity; patients have been very receptive towards this technology; they understand this better and are less skeptical; concerned with reliability.

100% of the respondents said image guided procedures would be widely used in the next 5-10 years.

What applications will image guided procedures be widely use for in the next decade? When will they be introduced?

Surgical guidance 1-3 years; targeting of parenchimal space occupying lesions 3 years; joint surgery 1-2 years; biopsy of intra abdominal organs 5 years; radiation treatment, minimally invasive scope surgery, neurosurgery, biopsy, international radiology & M.I.T. 1-3 years; MRT: focused US, CRYORX, Laser IS 2 years; CT fluoroscopy - cone beam & area detectors 3 years; frameless stereotaxy 3 years; surgery under the guidance of CT 1-2 years; surgery under the guidance of MRI.

If you think Image-guided procedures will not be widely used over the next decade, why not?

Cost

40% of the physicians are currently using image guided procedures.

If you are a physician and don't use image guided procedures, why not?

Not available; down sizing of computer; easy handling of the system; financial (insurance) support of it's use; cost

What are the top technical problems with image guided procedures?

Image registration; real time updates; use in soft tissues; reliability; speed; none; computer vision improvements; on-line segmentation; medical image improvements (x-ray...); ease of use including augmented reality (microscopes & endoscopes); validation and improved accuracy within a procedure; MR Interventional Systems (Open MR, MRT); image volume fusion (electronic atlas); cone beam CT scanner; faster image processing; better imaging; integration with therapy devices; outcome study; fidelity; registration/fusion of multimodal information; better tracking technology; formalized safety assessment methods; methods to assure software integrity; integration of pre-op planning with surgical procedures; cost of CT scans; miniaturization of sensors.

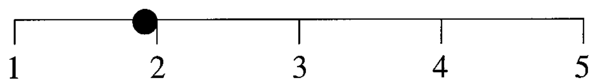
What are the top regulatory problems with image guided procedures?

Reimbursement; reduced cost; access to image and other information that really works; regulatory framework that does not inhibit innovation; proof of benefit - by rigorous methods (RCT); medical acceptance; increased acceptance of effectiveness & importance; medico-legal; clinical lagapathy; appropriate evaluation and testing; training and regulations for use; methods of sharing risk & liability between professional bodies; confidence in the business sector; education of physicians as to benefits of FDA approved devices; insurance company reluctance to support investigational studies; cost of FDA submission; published policy for FDA.

J.3 Surgical Simulators

On a scale from 1 - 5 (5 being very difficult) how difficult has it been to convince medical colleagues, research colleagues and patients (if applicable) to support surgical simulators?

Medical Colleagues:

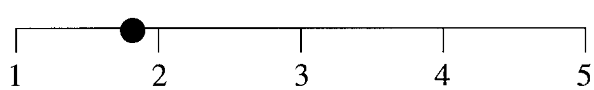


Medical Colleagues: 1.95

What are the main areas of resistance from medical colleagues?

Lack of useful prototypes; reliability and ease of use; relevant information; cost/availability; complex to use (requires expertise in computer graphics, too slow); time required; not being able to incorporate all clinical situations in the planning; suspicion of "high tech" procedures; lack of training programs; time many colleagues not planning the interventions formally; insuring that the simulation (even when integrated with data) is as real as possible and is not "creating" impossible situations; realistic methods to enable touch sensation; computation/ speeds; lack of perceived value over current planning methods; lack of faith in simulator really providing realistic environment for training and pretreatment planning; show definite advantages; ability to execute plans; additional procedures induce additional work load in the first step; conventional planning is very time-effective; "Good idea but how does it apply to me?"; running the software on inexpensive platforms; the development of detailed tests of the simulators; Pre-op planning takes "too much time" for some clinical colleagues; obstinance: "I don't need this"; fear of computers; lack of intent/cooperation from data acquisition personnel.

Research Colleagues:

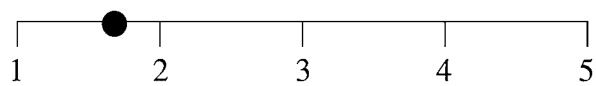


Research Colleagues: 1.81

What are the main areas of resistance from research colleagues?

Introduction of clinical principles; lack of clinical expertise; accuracy - validity; repeatability - precision; cost; not basic science enough; reluctance to use standard software; more realistic models vs. assembling all the needed parameters and computation time; skeptical that medical community will not accept them if they really don't simulate actual clinical environment; funding; adequacy with needs; imaging problems; bringing together researchers and clinicians to determine goals; high cost of computer platforms; expertise required to run application programs; reluctance to leave known methods; absence of normative database; absence of analysis conventions.

Patients:



Patients: 1.69

What are the main areas of resistance from patients?

Sometimes used in cases where benefits are dubious (e.g., cleft palate); How to carry out the precision provided by the computer model analysis; cost for the patient; no problem; patients are very receptive; none; families and older patients recognize the skill icon and I finally get consent.

95% of the respondents said surgical simulators would be widely used in the next 5-10 years.

What applications will Surgical Simulators be widely use for in the next decade? When will they be introduced?

Basic skill practice 5 years; rehearsal of uncommon procedures 8 years; image augmentation 8 years; train medical support specialists 2-3 years; sinus/head & neck surgery/cranio-facial (endosurgery, especially) 3-4 years; dexterity training & measurement for minimally invasive surgery (laparoscopy, endoscopy, etc.) 2-4 years; 3D surgical maneuver simulation 3 years; skull base surgery 1-2 years; neurosurgery 1-2 years; some forms of radiotherapy ~3 years; urology 5years; determine accuracy of procedures 2-4 years; integrate function of surgical teams 3-6 years; gesture training for Laparoscopy 2 years.

If you think surgical simulators will not be widely used over the next decade, why not?

Not available in most specialties; lack of authenticity and complexity may limit usefulness of trainers in laparoscopic surgery; lack of fidelity; the whole concept of surgical planning does not seem consistent with most surgeon's personalities; most surgeons will not take the time to do planning prior to a surgery; what is needed is a device that seamlessly integrates with the surgical act that allows the surgeon to do planning on the fly; no proof; reasonable cost/benefit ratio

24% of the physicians are currently using surgical simulators.

If you are a physician and don't use a surgical simulator, why not?

No useful system; not available in my specialty; cost; we have intra-operative surgical localization devices that allow us to plan surgery on the fly intra-operatively; Systems unavailable due to simplicity

What are the top technical problems with surgical simulators?

Photo-realistic graphics or equivalent; deformability/fluid motion; haptic interface; sensors; computer graphic refinement; availability; improved haptic interfaces; robust systems; realistic nonlinear tissue behavior; none; down sizing of computer; digital transfer to the computer; realistic display; ease of use; ergonomically related to surgical procedure; proof of benefits; registration to patient; enhanced reality; performance of image processing; improvement of image quality; reliability; improved automated & semi-automated segmentation; more interdisciplinary research activity reliable stereoscopic head mounted display; high resolution photographic-type quality computer displays; planners must be automated; real time interactive response; ability to carry out planned intervention; infrastructure; multi-application usability; reliable and automatic reconstruction; biomechanical and physiological simulation.

What are the top regulatory problems with surgical simulators?

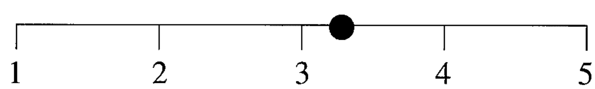
Surgery as a skill (vs. an art); quantitative assessment of performance liability; safety; confidentiality; change in resident training program philosophy; cost-effectiveness; recognition of the need for specialized training (lecture, laboratories, exercises, etc.); none; daily and routine use of computer by doctors; standards of information exchange that really work; ensuring regulatory changes do not stifle innovation; proof that systems are safe and efficacious; clinical measures; increased acceptance of effectiveness & importance; more data on cost-benefit to persuade purchasers; interstate license/regulation; medico-legal; clinical lagapathy; surgeons have to accept the use of off-line training; general adoption of computer savvy on the part of

surgeons; increasing demands for surgeons to perform continuing medical education; routine presence of computers in operating suites; medical insurance; engineers must apply solution not technology; get acceptance that simulators can be used for accreditation; clarify FDA policy on software.

J.4 Robotics / Manipulators

On a scale from 1 - 5 (5 being very difficult) how difficult has it been to convince medical colleagues, research colleagues and patients (if applicable) to support robotics / manipulators?

Medical colleagues:

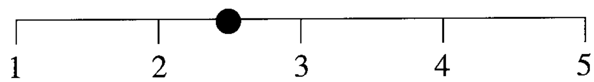


Medical Colleagues: 3.25

What are the main areas of resistance from medical colleagues?

Fear of loss of control; Lack of data demonstrating equivalent outcomes and benefits; small changes in current procedures (additional information sources, improved instruments) are easy; major changes are difficult; fear of complexity; cost justification; lack of space in OR; reluctance to admit that current procedures are difficult; credibility; robustness; reliability; relevance; lack of proof for benefits; most haven't thought about how to use it; lack of effective PAGS/IMAC systems liability or time consumption; lack of an understanding of what can be done; surgeons are very concerned about the safety of this technology and the possible impact it will have on their financial bottom line; awkwardness of current technology; lack of availability of user friendly systems; developing systems to fit individual surgical environments and needs; comparative advantage; efficiency; Colleagues think the process too complicated; impractical; too far in future; people are resistant to robots due to registration errors; FDA approval; learning curve; lack of demonstrated clinical/cost benefits; science fiction image of robots.

Research colleagues:

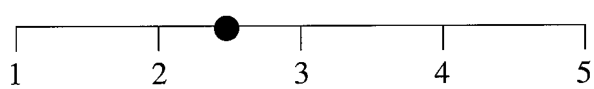


Research Colleagues: 2.46

What are the main areas of resistance from research colleagues?

Generally eager to get involved; technical feasibility; doubtful academic value; "solution in search of a problem; need to build up the basic data; cost; an assurance that all reasonable design considerations have been made; only recently in Europe are standards being developed; it has been extremely difficult dealing with the politics between companies and the appropriate desire to protect one's intellectual property; technical problems and fail safe clinical requirements - big tasks - not easy to approach and overcome; funding in medical robotics has been limited; transition from lab prototype to real product seems unclear; coemption from optical tracking systems.

Patients:



Patients: 2.35

What are the main areas of resistance from patients?

Patient's are very willing and exciting; high cost; low availability; loss of personal contact with physician; there have note been any medical robotic devices available for clinical use; or even research use in neurosurgery; will it work for me; patients want robotics to assist only, not to do; in UK patients trust, science fiction image of robots concerns about safety.

Due to an error, the following questions were never asked on the questionnaire. We are sorry any inconvenience or problems this may introduce.

What applications will robotics / manipulators be widely use for in the next decade? When will they be introduced?

If you don't think robotics / manipulators will be widely used over the next decade, why not?

If you are a physician and don't use robotics/manipulators, why not?

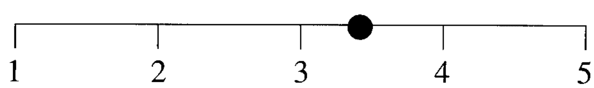
What are the top technical problems with robots / manipulators?

What are the top regulatory problems with robots / manipulators?

J.5 Teleinterventions

On a scale from 1 - 5 (5 being very difficult) how difficult has it been to convince medical colleagues, research colleagues and patients (if applicable) to support teleinterventions?

Medical colleagues:

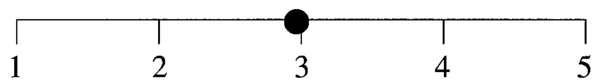


Medical Colleagues: 3.20

What are the main areas of resistance from medical colleagues?

Novel technology; no clinical trials; fear of lack of redundancy in case of system break down; lack of data; medicolegal issues; cost; anticipation that collective small improvements to more conventional methods would obviate teleoperation's advantages; scepticism -- haven't seen teleop. systems that work as well as direct manipulation; loss of control, esp. in emergencies; relevance; technical feasibility; uncertain need for technology, especially in urban hospitals; data/image transmission; lack of training programs; no network; complex; restricted by bandwidth; over enthusiasm/expectations; demonstrating usefulness; ethical/legal concerns.

Research colleagues:

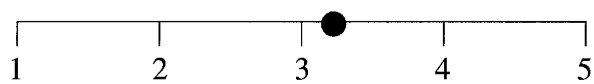


Research Colleagues: 2.95

What are the main areas of resistance from research colleagues?

none listed

Patients:



Patients: 3.17

What are the main areas of resistance from patients?

Concern that primary physician is not in the O.R. or that someone unknown is doing surgery; is it safe? any other way to do this; loss of personal contact with physician; easy for telediagnosis; telesurgery remains experimental

51% of the respondents said teleinterventions would be widely used in the next 5-10 years.

What applications will teleinterventions be widely use for in the next decade? When will they be introduced?

Minimal access surgery 3 years; micro/endo surgery 5 years; remote surgery 8 years; interventional diagnostic procedures in contaminated areas; space missions, ambulances 5 years; robotization of surgical tools 2 years; military - triage 10 years; microsurgery (opthamology, neurosurgery) over short distance (same room) 5-10 years; too many major technical problems to overcome in that time period, far apart islands 4-5 years; rural/remote emergencies 3 years; 3rd world/military/warfare 2 years; super-specialization 5 years; teleconsultation 3-4 years; remote instructional courses 5-10 years; telementoring will increase 5-10 years; biopsy apparatus 1-2 years; removal of foreign objects in airway and upper GI tract 5yrs

If you think that teleinterventions will not be widely used over the next decade, why not?

Lack of communication infrastructure; social resistance; initial cost; there are not enough obvious potential applications that are not more cost-effectively handled by 1) on-site semi-skilled and mentored staff or 2) transport to a medical center; patient through-put must be high to justify expensive equipment; surplus of surgeons; surgeons should be sufficiently trained; reliability of computer and communication systems is not enough in emergency; the advantages are not so great that wide use will occur within 10 years; regulatory requirements; regulation bodies will require considerable reassurance of the reliability; too risky and technologically too complex; In most places local surgeons would be available with sufficient experience; development of reliable systems need more time; clinical added value often unclear.

14% of the physicians are currently using teleinterventions.

If you are a physician and don't use teleinterventions, why not?

No need presently for telesurgery; not in the philosophy of my group; doubtful value in an academic medical center/urban setting; not available yet; lack of national "new" ambulance service; no facilities available.

What are the top technical problems with teleinterventions?

Enhanced displays; increased DOF; improved telecommunication networks regionally and globally; robotic end effector development; lower cost technology; dexterity; flexible visualization with variable point of view; safety; robustness; speed; immersion in realistic environment; compact; easy-to-use; surgical implements & appliances; visual & other forms of feedback surgeons are completely comfortable with; reliability of systems; micro-sensors and actuators; head mounted stereoscopic displays; integration with other information; bio compatibility; materials; on site skilled surgeon.

What are the top regulatory problems with teleinterventions?

Demonstration of cost effectiveness; acceptance of efficacy by medical groups; resolution of medicolegal issues; defined reimbursements/costs; licensing (state to state); reduced capital cost of equipment; on-site staff skilled to intervene surgically and to provide post-op care; limited medical license to practice (across state lines); perceived threat to local practitioners; equipment must past FDA test (IND, 510K, PMA...); medico-legal; confidence in the business community; legal concerns regarding malpractice.

	Technical problem or research need		
	Real-time 3D imaging	Robust registration of 2D to 3D images	creating/evaluating/validating usefulness
Why is this an important technical problem?	Navigation and monitoring in 3D is essential for safety and accuracy	3D modalities (CT, MRI, etc.) provide excellent information for treatment planning but are not practical for many surgical procedures. “Light-weight” imaging sensors such as video or x-ray fluoroscopy are 2D in nature.	At the base of many proposed application. It's difficult to know what's better without more direct comparison/evaluation. Rigorous testing on standardized data sets is often lacking in our field.
What are the difficulties?	Current systems are largely 2D or 2 1/3D, complex data acquisition & display problems have not been addressed.	Robustness-methods must work well and accurately without requiring massive fixturing (e.g., portable c-arm rather than biplanar machine). Efficiency-methods must work quickly on relatively low-cost equipment.	Requires organization, funding and someone willing to dedicate time to this. (some progress has already been made, though in the U.S., the NIH has funded comparison of registration algorithms). Getting researchers to agree on what a standard dataset is might be touch.
On a scale from 1 - 5 (5 very difficult) how difficult is it to overcome?	5	5	4
What is the probability it could be solved in 2 years?	10%	80%	50%
How many years will it take to solve and at what cost?	5 years at over $10 million per year	3 - 5 years at $1-10 Million per year	2 - 3 at $10 Million per year

Appendix K Working Group Issue/Topic Checklist

This document contains a checklist of topics and issues which each group should address during the working group sessions. Additional details of the items listed below can be found in the pre-workshop report. Each working group participant should familiarize themselves with the pre-workshop report section on their assigned application area. It is expected that the final workshop report will address the issues listed below for each application area. Of course, working groups should feel free to address issues / topics which are not contained on this checklist.

Enabling Technologies - building block technologies required for application development

- Augmented or hybrid reality displays
- Medical imaging technologies
- Non-medical sensing and imaging technologies
- Registration methods
- Medical image processing and understanding

Technical Issues - common to each of the application areas

- System validation and requirement specification
- Minimally invasive procedure design
- Design for safety

Non-Technical Issues - common to each of the application areas

- Clinical evaluation and cost benefit analysis
- Acceptance
- Regulatory issues
- Liability

Pre-workshop report questions: common issues

- What are the major technical problems and research needs in RCAMI?
- What areas in RCAMI are currently NOT receiving enough attention?
- What piece of technology do you wish that you had today?
- What are some of the key hurdles to overcome in sensing?
- What are some of the key hurdles to overcome in execution?
- What are some of the key hurdles to overcome in planning?
- What will be possible over the next 25 years?

Pre-workshop report questions: application areas

- What applications will *(your application area)* be widely use for in the next decade? When will they be introduced?
- If you think *(your application area)* will not be widely used over the next decade, why not?
- What are the top technical problems with *(your application area)*?
- What are the top regulatory problems with *(your application area)*?

Questions NOT included in the pre-workshop report

- List some of the current state of the art systems in *(your application area).*
- Where can collaboration between groups be established? How can overlap and repeated effort be reduced?
- What are the dependencies and overlaps with the other working groups? How can these be resolved?
- Is RCAMI really necessary? Are there alternatives which are simpler or less costly?
- List strengths and/or weaknesses of RCAMI.
- What are the next major areas of research towards which funding should be directed?

Terminology Definitions

- Surgical Simulators
    - Virtual reality
    - Surgical simulator
    - Physical modeling
    - Pre-treatment planning
- Image-Guided Procedures
    - Computer-assisted surgery
    - Computer-controlled surgery
    - Image-guided surgery
    - Robot-assisted surgery
- Robotics / Manipulators
    - Medical robot
    - Powered and unpowered robotic arm
    - Passive, semi-active and active robotic arm
    - Passive and/or Active compliance
    - Interventional robotic arm
- Teleintervention
    - Telepresence
    - Telemedicine
    - Telesurgery
    - Teleintervention
    - Telemanipulator
- Common Issues
    - Registration

- Calibration
- Augmented reality
- Hybrid reality
- Minimally invasive procedure

Appendix L Workshop Schedule

ARRIVAL - SUNDAY, JUNE 23, 1996

Participant's arrival/check in.

4:00	Welcome Reception - Drawing Room Speakers: Anthony DiGioia, Takeo Kanade and Peter Wells
6:00 p.m.	Happy Hour
7:00 p.m.	Dinner

DAY ONE - MONDAY, JUNE 24, 1996

7:15 a.m.	Full English Breakfast
9:00 -9:30 a.m.	Overview/Problem Definition Speakers: Anthony M. DiGioia and Takeo Kanade Keynotes' Address
9:30 - 10:00 a.m.	Edward Chao, Ph.D. - Surgical Simulators
10:00 - 10:30 a.m.	Russ Taylor, Ph.D. - Robotics/Manipulators
10:30 - 10:45 a.m.	Break
10:45 -11:15 a.m.	Philip Green, Ph.D. - Teleinterventions
11:15- 11:45 a.m.	Stephane Lavallee, Ph.D. - Image Guided Procedures
11:45- 12:50 p.m.	Special Session Speakers Safety Issues - Brian Davies Definitions - Patrick Finlay
12:50 -2:00 p.m.	Lunch
2:00 - 3:30 p.m.	Group Breakout
3:30 - 3:50 p.m.	Break
3:50 - 5:30 p.m.	Group Breakout
6:15 p.m.	Happy Hour
7:15 p.m.	Dinner
8:30 p.m.	MRC-LINK Keynote Lecturer - Drawing Room Speaker: Dr. Zigmund Krukowski

DAY TWO - TUESDAY, JUNE 25, 1996

7:00 a.m.	Full English Breakfast
8:00 a.m. -9:00	Group Leader Report
9:00 -11:30 a.m.	Group Breakout
11:30 - 12:30 p.m.	Group Leader Report
12:30 p.m.	Group Photograph - Location to be announced

12:45 - 1:30 p.m.	Lunch
1:30 - 7:00 p.m.	Recreation/Free Time
7:00 p.m.	Workshop Finale
	Speakers: Special Trustees for United Bristol Hospitals - Peter N.T. Wells
	National Science Foundation - Gil Devey
	U.S. Army - Major Conrad Clyburn

DAY THREE - WEDNESDAY, JUNE 26, 1996

7:00 a.m.	Full English Breakfast
8:00 - 8:45 a.m.	Special Session - Technology Transfer Opportunities
	Speakers: Faina Shtern, National Cancer Institute
8:45 - 10:30 a.m.	Group Breakout
10:30 - 10:50 a.m.	Break
10:50 - 11:50 a.m.	Group Leader Final Report
11:50 - 1:00 p.m.	Closing Remarks
1:00 - 2:00 p.m.	Lunch

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